according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2024/04/06

 3.0
 2024/09/28
 7213849-00011
 Date of first issue: 2020/10/30

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin For-

mulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number: 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: suspensionColour: white to off-whiteOdour: No data available

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. Toxic to aquatic life. May cause long lasting harmful effects to aquatic life.

GHS Classification

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Specific target organ toxicity -

repeated exposure

Category 2

Aspiration hazard : Category 1

Short-term (acute) aquatic

hazard

Category 2

1/21

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: 3.0 2024/09/28

SDS Number: 7213849-00011

Date of last issue: 2024/04/06 Date of first issue: 2020/10/30

Long-term (chronic) aquatic

hazard

Category 4

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.

H373 May cause damage to organs through prolonged or re-

peated exposure.

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 ad-

vice/ 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.

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

Physical and chemical hazards

Not classified based on available information.

Health hazards

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure. May be fatal if swallowed and enters airways.

Environmental hazards

Toxic to aquatic life. May cause long lasting harmful effects to aquatic life.

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)
Paraffin oil	8012-95-1	>= 70 -< 90
Benzylpenicillin	61-33-6	>= 10 -< 20
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 -< 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 ad-

vice 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.

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

May be fatal if swallowed and enters airways. May cause an allergic skin reaction.

delayed

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

May cause damage to organs through prolonged or repeated

exposure.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive 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

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.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version 3.0

Revision Date: 2024/09/28

SDS Number: 7213849-00011

Date of last issue: 2024/04/06 Date of first issue: 2020/10/30

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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation 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 as-

sessment

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 respira-

tory 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

Storage

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

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

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Paraffin oil	8012-95-1	TWA (Inhalable particulate matter)	5 mg/m3	ACGIH	
Benzylpenicillin	61-33-6	TWA	600 μg/m3 (OEB 2)	Internal	
	Further information: RSEN, DSEN				
		Wipe limit	100 μg/100 cm2	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/m3 (OEB 2)	Internal	
Dihydrostreptomycin sulphate	5490-27-7	TWA	0.4 mg/m3 (OEB 2)		
	Further information: OTO				
		Wipe limit	Not required		
Fatty acids, C14-26, aluminum salts	97404-28-9	TWA (Respirable particulate matter)	1 mg/m3 (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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

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

Hand protection

Material : Chemical-resistant gloves

Hygiene measures : If exposure to chemical is likely during typical use, provide

Work uniform or laboratory coat.

eye flushing systems and safety showers close to the work-

ing 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : white to off-white

Odour : No data available

Odour 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 : No data available

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

flammability limit

Vapour pressure : No data available

Relative vapour 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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : 300 - 16,000 mPa.s

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 Date of first issue: 2020/10/30 3.0 2024/09/28 7213849-00011

> 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

administration)

Acute toxicity (other routes of : LD50 (Mouse): 3,500 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 329 mg/kg Application Route: Intravenous

Sodium [2S-(2α,5α,6β)]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Acute oral toxicity : LDLo (Rat): > 5,000 mg/kg

Acute toxicity (other routes of : LD50 (Dog): 633 mg/kg

administration)

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

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

LD50 Oral (Mouse): 30,000 mg/kg

Fatty acids, C14-26, aluminum salts:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg

Method: OECD Test Guideline 423

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Paraffin oil:

Species : Rabbit

Result : No skin irritation

Fatty acids, C14-26, aluminum salts:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 431

Remarks : Based on data from similar materials

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Remarks : Based on data from similar materials

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Paraffin oil:

Species : Rabbit

Result : No eye irritation

Fatty acids, C14-26, aluminum salts:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

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

: Weak sensitizer Result

Test Type : Maximisation Test

Test Type
Exposure routes
Species : Dermal : 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)

Exposure routes : Skin contact
Species : Mouse
Method : OECD Test 0

: OECD Test Guideline 429: negative

Result

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzylpenicillin:

Germ cell mutagenicity -: Weight of evidence does not support classification as a germ

Assessment cell mutagen.

Sodium [2S-(2α,5α,6β)]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Germ cell mutagenicity -: Weight of evidence does not support classification as a germ

Assessment cell mutagen.

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

Dihydrostreptomycin sulphate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Test system: Human lymphocytes

Result: negative

Fatty acids, C14-26, aluminum salts:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Sodium [2S- $(2\alpha,5\alpha,6\beta)$]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Carcinogenicity - Assess- : Weight of evidence does not support classification as a car-

ment cinogen

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

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

Test Type: Fertility Species: Rabbit

Result: No effects on fertility

Effects on foetal develop-

ment

ment

ment

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 develop-

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 develop-

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

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

Effects on foetal develop- : Test Type: Reproduction/Developmental toxicity screening

ment

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 through prolonged or repeated exposure.

Components:

Dihydrostreptomycin sulphate:

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Paraffin oil:

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

Dihydrostreptomycin sulphate:

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

Symptoms : hearing loss

Species : Cat
LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 60 d
Target Organs : ear

Symptoms : ataxia, hearing loss, Reduced body weight

Species : Cat LOAEL : 300 mg/kg Application Route : Oral

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

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, bron-

chospasm, 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

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Paraffin oil:

Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

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

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Benzylpenicillin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 3.6 mg/l

Exposure time: 48 hrs

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Raphidocelis subcapitata (freshwater green alga)): >

100 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50

mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

EC50 (blue-green algae): 0.74 mg/l

Exposure time: 72 hrs

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2024/09/28 7213849-00011 Date of first issue: 2020/10/30 3.0

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 tox- : 1

Toxicity to microorganisms : EC50: > 500 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 5 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Benzylpenicillin:

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-: log Pow: > 4

Remarks: Calculation octanol/water

Fatty acids, C14-26, aluminum salts:

Partition coefficient: n-: log Pow: > 7

octanol/water Remarks: Calculation

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 Date of first issue: 2020/10/30 3.0 2024/09/28 7213849-00011

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

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

Environmentally hazardous no

IATA-DGR

UN/ID No. Not applicable Not applicable Proper shipping name Not applicable Class Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable Not applicable

Packing instruction (cargo

aircraft)

Packing instruction (passen-Not applicable

ger aircraft)

IMDG-Code

UN number Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Not applicable Packing group Not applicable Not applicable Labels **EmS Code** Not applicable

Marine pollutant no

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

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

Not applicable for product as supplied.

National Regulations

GB 6944/12268

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

Marine pollutant : no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de-

termination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under : Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

DSL : not determined

AICS : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2024/09/28

Further information

Sources of key data used to compile the Safety Data

compile the Safety Data Sheet Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, 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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized 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 Substanc-

according to GB/T 16483 and GB/T 17519



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 7213849-00011 Date of first issue: 2020/10/30

es; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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.

CN / EN