according to GB/T 16483 and GB/T 17519



# **Benzylpenicillin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 5.0 2024/09/28 3928977-00024 Date of first issue: 2019/01/02

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Benzylpenicillin Formulation

Other means of identification : Duplocillin LA (A004183)

Depocillin (A004256)

DEPOCILLIN PROCAINE PENICILLIN 300MG/ML INJECTION

(37258)

DUPLOCILLIN PROCAINE AND BENZATHINE PENICILLIN

INJECTION (37266)

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 : suspension Colour : white

Odour : No data available

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

**GHS Classification** 

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic : Category 3

according to GB/T 16483 and GB/T 17519



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hazard

**GHS** label elements

Hazard pictograms





Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H400 Very toxic to aquatic life.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P261 Avoid breathing 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:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

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.

P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

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.

**Environmental hazards** 

Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

according to GB/T 16483 and GB/T 17519



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#### 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)	
Benzylpenicillin	61-33-6	>= 30 -< 50	

#### 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, remove to fresh air. If inhaled

> If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

In case of contact, immediately flush skin with soap and plenty In case of skin contact

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

Flush eyes with water as a precaution. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

> Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms May cause an allergic skin reaction.

and effects, both acute and

delayed

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

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

tive airways dysfunction syndrome).

First Aid responders should pay attention to self-protection, Protection of first-aiders

> 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 None known.

according to GB/T 16483 and GB/T 17519



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media

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, protective equipment and emergency 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.

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

according to GB/T 16483 and GB/T 17519



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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.

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.

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.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

	-				
Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Benzylpenicillin	61-33-6	TWA	600 μg/m3 (OEB	Internal	
			2)		
	Further information: RSEN, DSEN				
		Wipe limit	100 µg/100 cm2	Internal	

**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-

according to GB/T 16483 and GB/T 17519



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ommended guidelines, use respiratory protection.

Filter type : Particulates type

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.

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

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

according to GB/T 16483 and GB/T 17519



# **Benzylpenicillin Formulation**

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Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

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- : Can react with strong oxidizing agents.

tions

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 Ingestion Eye contact

according to GB/T 16483 and GB/T 17519



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#### **Acute toxicity**

Not classified based on available information.

### **Components:**

#### Benzylpenicillin:

Acute oral toxicity : LD50 (Rat): 8,000 mg/kg

LD50 (Mouse): > 5,000 mg/kg

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

administration)

Application Route: Intraperitoneal

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

#### Skin corrosion/irritation

Not classified based on available information.

### Serious eye damage/eye irritation

Not classified based on available information.

### Respiratory or skin sensitisation

### Skin sensitisation

May cause an allergic skin reaction.

### **Respiratory sensitisation**

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

### **Components:**

## Benzylpenicillin:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Dermal Species : Mouse

Result : Weak sensitizer

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig Result : positive

Remarks : Based on data from similar materials

Result : Strong sensitizer

Remarks : Based on human experience.

### Germ cell mutagenicity

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



# **Benzylpenicillin Formulation**

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### **Components:**

## Benzylpenicillin:

Germ cell mutagenicity -

Assessment

: Weight of evidence does not support classification as a germ

cell mutagen.

### Carcinogenicity

Not classified based on available information.

# Reproductive toxicity

Not classified based on available information.

### **Components:**

### Benzylpenicillin:

Effects on fertility : Test Type: Fertility

Species: Mouse

Result: No effects on fertility

Test Type: Fertility

Species: Rat

Result: No effects on fertility

Test Type: Fertility Species: Rabbit

Result: No effects on fertility

Effects on foetal develop-

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

### STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

Not classified based on available information.

# Aspiration toxicity

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### **Experience with human exposure**

**Components:** 

Benzylpenicillin:

Inhalation : Symptoms: Allergic reactions, Abdominal pain, bron-

chospasm, skin rash

#### 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

### **Components:**

Benzylpenicillin:

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

Exposure time: 96 hrs

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 hrs

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

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

100 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

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

mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

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

Exposure time: 72 hrs

Method: OECD Test Guideline 201

NOEC (blue-green algae): 0.14 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

icity)

Toxicity to microorganisms : E

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

according to GB/T 16483 and GB/T 17519



# **Benzylpenicillin Formulation**

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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

**Bioaccumulative potential** 

No data available

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 : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Benzylpenicillin)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Benzylpenicillin)

Class : 9 Packing group : III

according to GB/T 16483 and GB/T 17519



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Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

r aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

964

(Benzylpenicillin)

Class : 9
Packing group : III
Labels : 9

EmS Code : F-A, S-F Marine pollutant : yes

### 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 : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Benzylpenicillin)

Class : 9
Packing group : III
Labels : 9
Marine pollutant : no

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 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)

according to GB/T 16483 and GB/T 17519



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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

Yangtze River Protection Law

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

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

**AICS** not determined

DSL 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 Sheet

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

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

Internal technical data, data from raw material SDSs, OECD

Date format : yyyy/mm/dd

Full text of other abbreviations

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

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x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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