

Benzylpenicillin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 3.1 28.09.2024 3928972-00022 Date of first issue: 02.01.2019

SECTION 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 name of supplier : MSD

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@msd.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

Respiratory sensitization : Category 1

Skin sensitization : Category 1

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 diffi-

culties if inhaled.

Precautionary Statements : Prevention:

P261 Avoid breathing mist or vapors.

P272 Contaminated work clothing should not be allowed out of

the workplace.

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.



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P333 + P313 If skin irritation or rash occurs: Get medical advice/

attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Benzylpenicillin	61-33-6	>= 30 -< 50	

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.

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

Most important symptoms and effects, both acute and

delayed

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

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

reactive 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.



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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.

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 fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective agreement and amor

tive 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.



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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.

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.

Take care to prevent spills, waste and minimize release to the

environment.

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

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled 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

Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis	
		exposure)	concentration		
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-



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less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Color : 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



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Relative vapor density No data available

Relative density No data available

Density No data available

Solubility(ies)

Water solubility soluble

Partition coefficient: n-

octanol/water

No data available Autoignition temperature

No data available Decomposition temperature

Viscosity

Viscosity, kinematic No data available

Explosive properties Not explosive

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

Not applicable

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. Can react with strong oxidizing agents.

Possibility of hazardous reac- :

tions

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:

Benzylpenicillin:

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



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

Acute toxicity (other routes of :

administration)

LD50 (Mouse): 3,500 mg/kg

Application Route: Intraperitoneal

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

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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.

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.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.



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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.

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.

Experience with human exposure

Components:

Benzylpenicillin:

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

chospasm, skin rash

SECTION 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



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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

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

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available



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SECTION 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

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 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

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

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.

Domestic regulation

NOM-002-SCT

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.



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(Benzylpenicillin)

Class : 9
Packing group : III
Labels : 9

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.

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

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 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



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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

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/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8