

Benzylpenicillin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 4.1
 28.09.2024
 3928978-00023
 Date of first issue: 02.01.2019

SECTION 1. 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 : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

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

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 3

GHS label elements

Hazard pictograms



*

Signal Word : Danger



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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 vapors.

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.

Other hazards which do not result in classification

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.



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Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

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

Most important symptoms

In case of eye contact

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).

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.

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.

Description of the second seco

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 emer-

gency 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.



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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 Advice on safe handling Use only with adequate ventilation. 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.

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 parameters / Permissible	Basis
		exposure)	concentration	



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Benzylpenicillin	61-33-6	TWA	600 μg/m3 (OEB 2)	Internal		
	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

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

Hygiene measures

Work uniform or laboratory coat.

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

Color : white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available



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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 : soluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition 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

SECTION 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.



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Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

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 :

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



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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.

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.



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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

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

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

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



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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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste Contaminated packaging

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

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

(Benzylpenicillin)

Class 9 Ш Packing group Labels Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

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

(Benzylpenicillin)

Class 9 Packing group Ш

Miscellaneous Labels

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

964

964

Environmentally hazardous yes



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IMDG-Code

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Benzylpenicillin)

Class 9 Ш Packing group 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.

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

Argentina. Carcinogenic Substances and Agents Not applicable

Registry.

Control of precursors and essential chemicals for the Not applicable

preparation of drugs.

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

Further information

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

Full text of other abbreviations



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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 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

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.

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