

according to the Globally Harmonized System

Benzylpenicillin Formulation

	ast issue: 06.07.2024 irst issue: 02.01.2019
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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 d	eta	ils
Company	:	MSD

Address	:	Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207
Telephone	:	+1-908-740-4000
Emergency telephone number	:	+1-908-423-6000

E-mail address : E	EHSDATASTEWARD@msd.com
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Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Respiratory sensitisation	:	Category 1
Skin sensitisation	:	Category 1
Short-term (acute) aquatic hazard	:	Category 1
Long-term (chronic) aquatic hazard	:	Category 3

GHS label elements

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Haza	rd pictograms		*
Signa	l word	: Danger	V
Haza	rd statements	H334 May cau difficulties if inl H400 Very tox	se an allergic skin reaction. se allergy or asthma symptoms or breathing naled. ic to aquatic life. to aquatic life with long lasting effects.
Preca	autionary statements	P260 Do not b P271 Use only P272 Contami the workplace P273 Avoid re P280 Wear pro	ntainer tightly closed. reathe mist or vapours. outdoors or with adequate ventilation. nated work clothing should not be allowed out c lease to the environment. otective gloves/ protective clothing. spiratory protection.
		P304 + P340 I keep comforta P333 + P317 I P342 + P316 I gency medical	F ON SKIN: Wash with plenty of water. F INHALED: Remove person to fresh air and ble for breathing. f skin irritation or rash occurs: Get medical help f experiencing respiratory symptoms: Get emer help immediately. Fake off contaminated clothing and wash it befo pillage.
		Storage:	a wall ventilated place
		Disposal:	a well-ventilated place. of contents/ container to an approved waste

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture
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Components

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

4. FIRST AID MEASURES



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Gener	ral advice	:	vice immediate	accident or if you feel unwell, seek medical ad- ly. ns persist or in all cases of doubt seek medical
lf inha	led	:	If inhaled, remo If not breathing	, give artificial respiration. Jifficult, give oxygen.
In cas	e of skin contact	:	In case of conta of water. Remove conta Get medical att Wash clothing	act, immediately flush skin with soap and plenty minated clothing and shoes.
In cas	e of eye contact	:	Flush eyes with	n water as a precaution.
lf swa	llowed	:	If swallowed, D Get medical at	tention if irritation develops and persists. O NOT induce vomiting. tention if symptoms occur. toroughly with water.
	mportant symptoms ffects, both acute and ed	:	May cause an a May cause alle ties if inhaled. Excessive expo	allergic skin reaction. rgy or asthma symptoms or breathing difficul- osure may aggravate preexisting asthma and ry disorders (e.g. emphysema, bronchitis, reac-
Protec	ction of first-aiders	:	First Aid respondence and use the record	sfunction syndrome). nders should pay attention to self-protection, commended personal protective equipment ntial for exposure exists (see section 8).
Notes	to physician	:		atically and supportively.
5. FIREFIG	HTING MEASURES			
Suitab	ble extinguishing media	:	Water spray Alcohol-resista Carbon dioxide Dry chemical	
Unsui media	table extinguishing	:	None known.	
Specit fightin	fic hazards during fire- g	:	Exposure to co	mbustion products may be a hazard to health.
Hazar ucts	dous combustion prod-	:	Carbon oxides Metal oxides	
Specii ods	fic extinguishing meth-	:	cumstances an Use water spra	ing measures that are appropriate to local cir- id the surrounding environment. iy to cool unopened containers. naged containers from fire area if it is safe to do
	al protective equipment afighters	:		fire, wear self-contained breathing apparatus. protective equipment.

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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. 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 contain- ment 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 dis- posal 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

Technical measures Local/Total ventilation Advice on safe handling		See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. 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. 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.
Conditions for safe storage	:	Keep in properly labelled containers. Keep tightly closed.
Materials to avoid	:	Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

	-			
Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Benzylpenicillin	61-33-6	TWA	600 µg/m3 (OEB	Internal
			2)	
	Further informa	ation: RSEN, DS	EN	
		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 equipm	ent	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type
Hand protection	•	
Material	:	Chemical-resistant gloves
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

: suspension

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	Colour		:	white	
	Odour		:	No data available	1
	Odour ⁻	Threshold	:	No data available	
	рН		:	No data available	
	Melting	point/freezing point	:	No data available	
	Initial be range	oiling point and boiling	:	No data available	
	Flash p	oint	:	No data available	
	Evapor	ation rate	:	No data available	
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	No data available	
	Relative	e vapour density	:	No data available	
	Relative	e density	:	No data available	
	Density	,	:	No data available	
	Solubili Wat	ty(ies) er solubility	:	soluble	
	Partition octanol	n coefficient: n- /water	:	Not applicable	
		nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
		ng properties	:		mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	•

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Particle Particle	e characteristics e size	:	Not applicable	
. STABIL	ITY AND REACTIVITY	,		
Possib tions	vity cal stability ility of hazardous reac- ons to avoid	::	Stable under n	is a reactivity hazard. ormal conditions. strong oxidizing agents.
Incomp	atible materials lous decomposition	:	Oxidizing agen	ts decomposition products are known.
. TOXICO	LOGICAL INFORMAT	101	1	
Informa exposu	ation on likely routes of Ire	:	Inhalation Skin contact Ingestion Eye contact	
Not cla	toxicity ssified based on availa	ble	information.	
	onents:			
	penicillin: pral toxicity	:	LD50 (Rat): 8,00)0 ma/ka
	Jartoniny	•	LD50 (Mouse):	
	oxicity (other routes of stration)	:	LD50 (Mouse): Application Rou	3,500 mg/kg te: Intraperitoneal
			LD50 (Mouse): Application Rou	
••••••	orrosion/irritation	bla		
Seriou	ssified based on availa s eye damage/eye irri	tati	on	
	ssified based on availa			
Respir	atory or skin sensitis	atio	n	
	ensitisation use an allergic skin rea	actic	n.	
-	atory sensitisation		ntomo or broathi	ng difficulties if inhaled.

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

Components:

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Not classifie Componen Benzylpen Germ cell n Assessmen Carcinoger Not classifie Reproduct	outes mutagenicity ed based on avail	: : : : : :	Local lymph node Dermal Mouse Weak sensitizer Maximisation Tes Dermal Guinea pig positive Based on data fro Strong sensitizer Based on human	st om similar materials
Exposure ro Species Result Remarks Germ cell n Not classifie Componen Benzylpen Germ cell n Assessmen Carcinoger Not classifie Reproduct Not classifie Componen Benzylpen	mutagenicity ed based on avail	: : : :	Dermal Guinea pig positive Based on data fro Strong sensitizer	om similar materials
Remarks Germ cell r Not classifie Componen Benzylpen Germ cell r Assessmen Carcinoger Not classifie Reproduct Not classifie Componen Benzylpen	ed based on avail	: : able		
Not classifie Componen Benzylpen Germ cell n Assessmen Carcinoger Not classifie Reproduct Not classifie Componen Benzylpen	ed based on avail	able		-
Benzylpen Germ cell n Assessmen Carcinoger Not classifie Reproduct Not classifie <u>Componen</u> Benzylpen	<u>its:</u>	abio	information.	
Not classifie Reproduct Not classifie <u>Componen</u> Benzylpen	nutagenicity -	:	Weight of eviden cell mutagen.	ce does not support classification as a germ
<u>Componen</u> Benzylpen	ed based on availative toxicity			
Benzylpen	ed based on avail	able	information.	
		:	Test Type: Fertili Species: Mouse Result: No effects	s on fertility
			Test Type: Fertili Species: Rat Result: No effects Test Type: Fertili	s on fertility
			Species: Rabbit Result: No effects	s on fertility
Effects on f ment	oetal develop-	:	Test Type: Devel Species: Mouse Result: No effects	opment s on foetal development
			Test Type: Devel Species: Rat Result: No effects	opment s on foetal development
			Test Type: Devel Species: Rabbit	opment

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	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.									
Ехр	erience with human exp	osi	ure							
Con	nponents:									
Ben	zylpenicillin:									
Inha	alation	:	Symptoms: Allerg chospasm, skin ra	ic reactions, Abdominal pain, bron- ish						
12. ECO	LOGICAL INFORMATION	N								
Eco	toxicity									
Con	nponents:									
Ben	zylpenicillin:									
Тох	icity to fish	:	LC50 (Oncorhync Exposure time: 96 Method: OECD Te							
	icity to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te							
Tox plan	icity to algae/aquatic its	:	EC50 (Raphidoce 100 mg/l Exposure time: 72 Method: OECD Te							
			NOEC(Raphidoo mg/l Exposure time: 72 Method: OECD Te							
			EC50 (blue-greer Exposure time: 72 Method: OECD Te							
			NOEC (blue-gree Exposure time: 72 Method: OECD Te							
M-F icity	`	:	1							

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	Toxicity	to microorganisms	:	EC50: > 500 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition
				NOEC: 5 mg/l Exposure time: 3 Test Type: Respir Method: OECD To	ation inhibition
	Persist	ence and degradabili	ity		
	<u>Compo</u>	onents:			
	-	penicillin:			
	Biodegi	radability	:	Result: Readily bi Biodegradation: 7 Exposure time: 28 Method: OECD To	70.10 %
		umulative potential a available			
		y in soil a available			
		adverse effects a available			
13. E	DISPOS	AL CONSIDERATION	IS		
	Dispos	al methods			
	Waste f	rom residues	:	Do not dispose of	waste into sewer. ordance with local regulations.
	Contam	ninated packaging	:	Empty containers dling site for recyc	should be taken to an approved waste han-
14. 1	RANSE	PORT INFORMATION			
	Interna	tional Regulations			
	UNRTD	-			
	UN nun Proper	nber shipping name	:	UN 3082 ENVIRONMENTA N.O.S.	LLY HAZARDOUS SUBSTANCE, LIQUID,
	Class Packing	a droup	:	(Benzylpenicillin) 9 III	
	Labels	mentally hazardous	:	9 yes	



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UN Pro Cla Pa La Pa air Pa	TA-DGR I/ID No. oper shipping name ass cking group bels cking instruction (cargo craft) cking instruction (passen- r aircraft)	:	UN 3082 Environmentally h (Benzylpenicillin) 9 III Miscellaneous 964 964	azardous substance, liquid, n.o.s.
	vironmentally hazardous	:	yes	
UN	DG-Code I number oper shipping name	:	UN 3082 ENVIRONMENTA N.O.S. (Benzylpenicillin)	LLY HAZARDOUS SUBSTANCE, LIQUID,
Pa La En	ass cking group bels nS Code arine pollutant	:	9 III 9 F-A, S-F yes	

Transport in bulk according to IMO instruments

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.

15. REGULATORY INFORMATION

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

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	:	28.09.2024
Further information Sources of key data used to 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/





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

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 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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