

Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

4.1 30.09.2023 10011300-00000 Date 01115t issue. 00.07.2022	Version 4.1	Revision Date: 30.09.2023	SDS Number: 10811300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
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Section 1: Identification

Product name	:	Benzylpenicillin / Dihydrostreptomycin Sulphate Formulatio		
Manufacturer or supplier's details Company : MSD				
Address	:	33 Whakatiki Street - Private Bag Upper Hutt - New Zealand	J 908	
Telephone	:	0800 800 543		
Emergency telephone number	:	0800 764 766 (0800 POISON) CHEMCALL)	0800 243 622 (0800	
E-mail address	:	EHSDATASTEWARD@msd.com	1	
Recommended use of the ch	em	ical and restrictions on use		
Recommended use Restrictions on use	:	Veterinary product Not applicable		

Section 2: Hazard identification

GHS Classification		
Respiratory sensitisation	:	Category 1
Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (ear, Kidney, inner ear)
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. H361d Suspected of damaging the unborn child.



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version 4.1	Revision Date: 30.09.2023	SDS Number: 10811300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
			lamage to organs (ear, Kidney, inner ear) ged or repeated exposure if swallowed.
Precau	utionary statements	P202 Do not ha and understood P260 Do not br P264 Wash ski P270 Do not ea P272 Contamir the workplace. P280 Wear pro tion/ face prote	eathe mist or vapours. n thoroughly after handling. at, drink or smoke when using this product. hated work clothing should not be allowed out of tective gloves/ protective clothing/ eye protec-
		P304 + P340 IF keep comfortat P308 + P313 IF attention. P333 + P313 If vice/ attention.	ON SKIN: Wash with plenty of water. INHALED: Remove person to fresh air and le for breathing. exposed or concerned: Get medical advice/ skin irritation or rash occurs: Get medical ad- experiencing respiratory symptoms: Call a ER/ doctor.
		Storage: P405 Store loc Disposal: P501 Dispose o disposal plant.	ked up. of contents/ container to an approved waste

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)
Dihydrostreptomycin sulphate	5490-27-7	>= 20 -< 30
Benzylpenicillin	61-33-6	>= 20 -< 25
Sodium hydroxymethanesulphinate	149-44-0	>= 0.1 -< 1

Section 4: First-aid measures



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version 4.1	Revision Date: 30.09.2023	SDS Number: 10811300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
Gene	ral advice	vice immediate	accident or if you feel unwell, seek medical ad ely. ms persist or in all cases of doubt seek medica
lf inha	aled	If not breathing	ove to fresh air. g, give artificial respiration. difficult, give oxygen. tention.
In cas	se of skin contact	: In case of con of water. Remove conta Get medical at Wash clothing	tact, immediately flush skin with soap and plen minated clothing and shoes. ttention.
In cas	se of eye contact	: Flush eyes wit	h water as a precaution. tention if irritation develops and persists.
lf swa	llowed	Get medical at	DO NOT induce vomiting. ttention. noroughly with water.
	important symptoms ffects, both acute and ed	: May cause an May cause alle ties if inhaled. Suspected of o Causes damage exposure if sw Excessive exp other respirato	allergic skin reaction. ergy or asthma symptoms or breathing difficul- damaging the unborn child. ge to organs through prolonged or repeated
Prote	ction of first-aiders	: First Aid respo and use the re	onders should pay attention to self-protection, commended personal protective equipment ntial for exposure exists (see section 8).
Notes	to physician		natically 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. Remove undamaged containers from fire area if it is safe to do



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version	Revision Date: 30.09.2023	SDS Number:	Date of last issue: 04.04.2023
4.1		10811300-00006	Date of first issue: 08.07.2022

Special protective equipment for firefighters	:	so. Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.			
Section 6: Accidental release me	Section 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.			

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 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 assessment 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. 	



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version 4.1	Revision Date: 30.09.2023	SDS Number: 10811300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
Hygie	ene measures	 Take care to pre environment. If exposure to ch flushing systems place. When using do r Contaminated w workplace. Wash contamina The effective op engineering conta appropriate dego 	a or smoke when using this product. Vent spills, waste and minimize release to the memical is likely during typical use, provide eye a and safety showers close to the working not eat, drink or smoke. Ork clothing should not be allowed out of the ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, pwning and decontamination procedures, e monitoring, medical surveillance and the ative controls.
Cond	litions for safe storage	Keep tightly clos	labelled containers. ed. nce with the particular national regulations.
Mate	rials to avoid		the following product types:

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Dihydrostreptomycin sulphate	5490-27-7	TWA	0.4 mg/m3 (OEB 2)	
	Further information: OTO			
		Wipe limit	Not required	
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 expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type :	Particulates type



Version 4.1	Revision Date: 30.09.2023		S Number: 311300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
	nd protection Material	:	Chemical-resistar	nt gloves
Eye	e 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.	
Ski	n and body protection	:	Work uniform or la	aboratory coat.
Section	9: Physical and chemica	l pr	operties	
Ар	pearance	:	suspension	
Co	lour	:	off-white, white	
Od	our	:	No data available	9
Od	our Threshold	:	No data available	9
pН		:	5.0 - 7.2	
Me	Iting point/freezing point	:	No data available	9
Init ran	ial boiling point and boiling ge	:	No data available	9
Fla	sh point	:	No data available	9
Eva	aporation rate	:	No data available	9
Fla	mmability (solid, gas)	:	Not applicable	
Fla	mmability (liquids)	:	No data available	9
	per explosion limit / Upper nmability limit	:	No data available	9
	wer explosion limit / Lower nmability limit	:	No data available	9
Vaj	pour pressure	:	No data available	9
Re	lative vapour density	:	No data available	9
Re	lative density	:	No data available	9
De	nsity	:	1.14 - 1.18 g/cm ³	3
Sol	lubility(ies)			



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Versior 4.1	Revision Date: 30.09.2023		S Number: 311300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
	Water solubility	:	No data available	e
	rtition coefficient: n-	:	Not applicable	
	tanol/water ito-ignition temperature	:	No data available	e
De	ecomposition temperature	:	No data available	e
Vis	scosity Viscosity, kinematic	:	No data available	e
Ex	plosive properties	:	Not explosive	
O	idizing properties	:	The substance o	r mixture is not classified as oxidizing.
Мо	blecular weight	:	No data available	e
Pa	rticle size	:	No data available	e
Pa	rticle Size Distribution	:	D50 = 15 µm	
			D90 = 30 µm	

Section 10: Stability and reactivity

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products		None known. Oxidizing agents No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes	: Inhalation
	Skin contact
	Ingestion
	Eye contact

Acute toxicity

Not classified based on available information.

Components:

Dihydrostreptomycin sulphate:

Acute oral toxicity	:	LD50 (Rat): 9,000 - 25,000 mg/kg
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sion	Revision Date: 30.09.2023		9S Number: 811300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
			LD50 Oral (Mous	e): 30.000 ma/ka
-	/lpenicillin:			
Acute	oral toxicity	:	LD50 (Rat): 8,000) mg/kg
			LD50 (Mouse): >	5,000 mg/kg
	toxicity (other routes of istration)	:	LD50 (Mouse): 3, Application Route	
			LD50 (Mouse): 32 Application Route	
Sodiu	m hydroxymethanesu	phi	nate:	
	oral toxicity	-	LD50 (Rat): > 2,0 Method: OECD T	00 mg/kg est Guideline 423 substance or mixture has no acute oral to
Acute	dermal toxicity	:		00 mg/kg est Guideline 402 substance or mixture has no acute dermal
-	corrosion/irritation assified based on availa	ble	information.	
Comp	onents:			
Sodiu	m hydroxymethanesu	phi	nate:	
Speci		:	Rat	
Resul	t	:	No skin irritation	
	u <mark>s eye damage/eye irri</mark> assified based on availa			
Comp	onents:			
Sodiu	m hydroxymethanesul	phi	nate:	
Speci		:	Rabbit	
Resul [:] Metho		:	No eye irritation OECD Test Guide	eline 405
Respi	ratory or skin sensitis	atio	n	
Skin s	sensitisation			



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10811300-00006	Date of first issue: 08.07.2022

Respiratory sensitisation

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

Components:

Benzylpenicillin:

Test Type Exposure routes Species Result	:	Local lymph node assay (LLNA) Dermal Mouse Weak sensitizer
Test Type Exposure routes Species Result Remarks	:	Maximisation Test Dermal Guinea pig positive Based on data from similar materials
Result Remarks	:	Strong sensitizer Based on human experience.

Sodium hydroxymethanesulphinate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
		-

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

Dihydrostreptomycin sulphate:				
Genotoxicity in vitro :	Test Type: Chromosome aberration test in vitro Test system: Human lymphocytes Result: negative			
Benzylpenicillin:				
Germ cell mutagenicity - : Assessment	Weight of evidence does not support classification as a germ cell mutagen.			
Sodium hydroxymethanesulph	inate:			
Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative			
	Test Type: In vitro mammalian cell gene mutation test			



Version 4.1	Revision Date: 30.09.2023		0S Number: 811300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
			Method: OECD ⁻ Result: positive	Test Guideline 476
Geno	toxicity in vivo	:	Test Type: Mam cytogenetic assa Species: Mouse Application Rout	malian erythrocyte micronucleus test (in vivo ay) e: Intraperitoneal injection Test Guideline 474
	i cell mutagenicity - ssment	:	Positive result(s) genicity tests.	from in vivo mammalian somatic cell muta-
	i nogenicity lassified based on avai	lable	information.	
Com	ponents:			
Dihyo	drostreptomycin sulp	hate		
	cation Route sure time EL	:	Rat Oral 2 Years 5 mg/kg body we negative	eight
-	oductive toxicity ected of damaging the	unbo	rn child.	
Com	ponents:			
Dihye	drostreptomycin sulp	hate:		
-	ts on foetal develop-	:	Test Type: Embl Species: Rabbit Application Rout Developmental Test Type: Embl Species: Guinea Application Rout General Toxicity weight Developmental Result: Maternal	Foxicity: NOAEL: 5 mg/kg body weight ryo-foetal development pig e: Intramuscular Maternal: LOAEL: 100 - 200 mg/kg body Foxicity: NOAEL: 10 mg/kg body weight toxicity observed., Embryotoxic effects and
				on the offspring were detected.
Benz	ylpenicillin:			
Effect	ts on fertility	:	Test Type: Fertil Species: Mouse Result: No effec	



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

sion	Revision Date: 30.09.2023	SDS Number: 10811300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022			
		Test Type: Ferti Species: Rat Result: No effec				
		Test Type: Ferti Species: Rabbit Result: No effec				
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 				
Sodiu	Im hydroxymethanes	ulphinate:				
Effect	s on fertility	reproduction/de Species: Rat Application Rou	Test Guideline 422			
Effect ment	s on foetal develop-	Species: Rat Application Rou	ryo-foetal development te: Ingestion Test Guideline 414			
Repro sessn	oductive toxicity - As- nent	: Some evidence animal experime	of adverse effects on development, based o			

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Components:

Dihydrostreptomycin sulphate:

Assessment

: Causes damage to organs through prolonged or repeated exposure.



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10811300-00006	Date of first issue: 08.07.2022

Repeated dose toxicity

Components:

Dihydrostreptomycin sulphate:						
Species	:	Guinea pig				
LÕAEL	:	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				
Exposure time		21 d				
Target Organs	:	ear				
Symptoms	:	ataxia, hearing loss, Reduced body weight				

Sodium hydroxymethanesulphinate:

Species	:	Rat
NOAEL	:	600 mg/kg
Application Route	:	Ingestion
Exposure time	:	13 Weeks
Method	:	OECD Test Guideline 408

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Dihydrostreptomycin sulpha	te:					
General Information	:	Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting, Headache, hypotension				
Benzylpenicillin:	Benzylpenicillin:					
Inhalation	:	Symptoms: Allergic reactions, Abdominal pain, bron- chospasm, skin rash				



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10811300-00006	Date of first issue: 08.07.2022

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 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- :	1
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
Sodium hydroxymethanesulph	ninate:
Toxicity to fish :	LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other :	EC50 (Daphnia magna (Water flea)): > 100 mg/l
	13 / 17



rsion	Revision Date: 30.09.2023		DS Number: 811300-00006	Date of last issue: 04.04.2023 Date of first issue: 08.07.2022
aquati	c invertebrates		Exposure time: 4 Method: OECD 1	8 h Fest Guideline 202
Toxicit plants	ty to algae/aquatic	:	Exposure time: 7	esmus subspicatus (green algae)): 370 m 2 h Fest Guideline 201
			Exposure time: 7	esmus subspicatus (green algae)): 10 mg '2 h Fest Guideline 201
Toxicit icity)	ty to fish (Chronic tox-	:	Exposure time: 3	rio (zebra fish)): 13.5 mg/l 5 d Fest Guideline 210
	ty to daphnia and other c invertebrates (Chron- city)	:	Exposure time: 2	nagna (Water flea)): 8 mg/l 1 d Fest Guideline 211
Toxicit	ty to microorganisms	:	NOEC: 10 mg/l Exposure time: 4	h
Persis	stence and degradabili	ty		
<u>Comp</u>	onents:			
Benzy	/Ipenicillin:			
Biode	gradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD 1	70.10 %
Sodiu	m hydroxymethanesu	lphi	inate:	
	gradability	:	Result: Readily b Biodegradation:	
			Exposure time: 2	
Bioac	cumulative potential			
<u>Comp</u>	onents:			
Sodiu	m hydroxymethanesu	lphi	inate:	
	on coefficient: n- bl/water	:	log Pow: < 0.3	
ociaric	, mator			



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10811300-00006	Date of first issue: 08.07.2022

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.
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.

Section 14: Transport information

International Regulations

UNRTDG		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
IATA-DGR		
UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passen- ger aircraft)	:	Not applicable
IMDG-Code		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable
	-	

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

Not applicable for product as supplied.

National Regulations

NZS 5433



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version	Revision Date: 30.09.2023	SDS Number:	Date of last issue: 04.04.2023
4.1		10811300-00006	Date of first issue: 08.07.2022
Prop Class Subs Pack Labe	sidiary risk king group	 Not applicable 	

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

not allocated

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

Section 16: Other information

Revision Date	:	30.09.2023
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/
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 con-



Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	10811300-00006	Date of first issue: 08.07.2022

centration; 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.

NZ / EN