

# **Ampicillin Formulation**

Vers 4.1	ion	Revision Date: 30.09.2023		S Number: 82441-00006		sue: 04.04.2023 sue: 27.10.2021
Sect	tion 1: lo	dentification				
	Product name		:	Ampicillin Formu	lation	
	Manufa	cturer or supplier's d	letai	ls		
	Compar	••	:	MSD		
	Address	3	:	33 Whakatiki Stro Upper Hutt - New		g 908
	Telepho	one	:	0800 800 543		
	Emerge	ncy telephone number	· :	0800 764 766 (08 CHEMCALL)	800 POISON)	0800 243 622 (0800
	E-mail a	address	:	EHSDATASTEW	/ARD@msd.cor	n
	Recom	mended use of the ch	nemi	ical and restriction	ons on use	
		nended use ions on use	:	Veterinary produ Not applicable	ct	
Sect	tion 2: F	lazard identification				
		assification				
		tory sensitisation	:	Category 1		
		ous to the aquatic ment - chronic hazard	:	Category 3		
	GHS la	bel elements				
		pictograms	:			
	Signal v	vord	:	Danger		

: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Hazard statements

Prevention:

P261 Avoid breathing mist or vapours. P273 Avoid release to the environment. P284 Wear respiratory protection.





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#### **Response:**

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

#### 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
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### Components

Chemical name	CAS-No.	Concentration (% w/w)
ampicillin	69-53-4	>= 10 -< 20

#### Section 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	:	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	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	:	
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	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
delayed		Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac- tive 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



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Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (0					
Unsuitable extinguishing		:	Dry chemical : None known.					
Spec	media Specific hazards during fire- fighting		Exposure to com	bustion products may be a hazard to health.				
	rdous combustion prod-	:	Nitrogen oxides ( Carbon oxides Sulphur oxides	NOx)				
Spec ods	Specific extinguishing meth- ods		<ul> <li>Use extinguishing measures that are appropriate to local cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe so. Evacuate area.</li> <li>In the event of fire, wear self-contained breathing apparat Use personal protective equipment.</li> </ul>					
Special protective equipment for firefighters		:						
ection 6	: Accidental release me	as	ures					
tive e	onal precautions, protec- quipment and emer- y procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal pro t recommendations (see section 8).				
Envir	onmental precautions	:	Prevent spreadin barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g. by containment or c se of contaminated wash water. should be advised if significant spillages				
	ods and materials for inment and cleaning up	:	For large spills, p ment to keep mat be pumped, store Clean up remaini bent. Local or national posal of this mate employed in the o	t absorbent material. rovide dyking or other appropriate contain- rerial from spreading. If dyked material can a recovered material in appropriate container ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- ations 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.



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	Il/Total ventilation ce on safe handling	<ul> <li>Use only with adequate ventilation.</li> <li>Avoid breathing mist or vapours. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and s practice, based on the results of the workplace exposure sessment Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory dise should consult their physician regarding working with res tory irritants or sensitisers. Take care to prevent spills, waste and minimize release environment.</li> </ul>				
Hygiene measures		flushing systems place. When using do r Wash contamina The effective op engineering con appropriate deg	nemical is likely during typical use, provide eye is and safety showers close to the working not eat, drink or smoke. ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, he monitoring, medical surveillance and the ative controls			
	ditions for safe storage	: Keep in properly Keep tightly close	labelled containers.			
Mate	erials to avoid	: Do not store with Strong oxidizing	n the following product types: agents			

#### Section 8: Exposure controls/personal protection

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis		
ampicillin	69-53-4	TWA	0.6 mg/m3 (OEB 2)	Internal		
	Further information: RSEN					

### Components with workplace control parameters

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.
		Laboratory operations do not require special containment.



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Perso	onal protective equipr	nent		
Resp	iratory protection	:	sure assessment	exhaust ventilation is not available or expo- demonstrates exposures outside the rec- lines, use respiratory protection.
	Iter type protection	:	Combined particu	ulates and organic vapour type
	aterial	:	Chemical-resista	nt gloves
Eye p	protection	:	If the work enviro mists or aerosols Wear a faceshield	ses with side shields or goggles. nment or activity involves dusty conditions, , wear the appropriate goggles. d or other full face protection if there is a et contact to the face with dusts, mists, or
Skin a	and body protection	:	Work uniform or I	aboratory coat.

#### **Section 9: Physical and chemical properties**

Appearance	:	suspension
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available



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Dens	sity	: No	o data available	9			
	bility(ies) /ater solubility	: No	o data available	9			
	tion coefficient: n-	: No	ot applicable				
	nol/water -ignition temperature	: No	No data available				
Deco	omposition temperature	: No	No data available				
	Viscosity Viscosity, kinematic		o data available	9			
Explo	osive properties	: No	Not explosive				
Oxid	Oxidizing properties		ne substance o	r mixture is not classified as oxidizing.			
Mole	Molecular weight		No data available				
Parti	Particle size		Not applicable				
Section 1	0: Stability and reactiv	ity					
Poor	stivity /	· NL	at alocalified as	a reactivity bazard			

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		

### Section 11: Toxicological information

Exposure routes	: Inhalation Skin contact
	Ingestion Eye contact

#### Acute toxicity

Not classified based on available information.

#### **Components:**

# ampicillin:

Acute oral toxicity

: LD50 (Rat): 10,000 mg/kg

LD50 (Mouse): 15,200 mg/kg



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	ute toxicity (other routes of ninistration)	:	LD50 (Rat): 6,200 Application Route	
			LD50 (Mouse): 4, Application Route	
	n corrosion/irritation t classified based on availa	able	information.	
	rious eye damage/eye irr t classified based on availa			
Re	spiratory or skin sensitis	satio	on	
	<b>n sensitisation</b> t classified based on availa	able	information.	
	<b>spiratory sensitisation</b> y cause allergy or asthma	syn	nptoms or breathing	difficulties if inhaled.
<u>Co</u>	mponents:			
am	picillin:			
	posure routes sult	:	Inhalation Sensitiser	
Ch	ronic toxicity			
	rm cell mutagenicity t classified based on availa	able	information.	
<u>Co</u>	mponents:			
	<b>picillin:</b> notoxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
				o mammalian cell gene mutation test ise lymphoma cells
				chromatid exchange assay nese hamster ovary cells
				nosomal aberration nese hamster ovary cells
			Test Type: Chron Test system: Hun Result: negative	nosomal aberration nan lymphocytes



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Genot	oxicity in vivo	: Test Type: M Species: Ra Application I Result: nega	Route: Oral		
Carcin	nogenicity				
Not cla	assified based on ava	ilable information.			
<u>Comp</u>	onents:				
ampic	illin:				
Specie Applic Expos	es ation Route ure time	: Rat : Oral : 2 Years : 750 mg/kg b	ody weight kaemia, breast tumors		
Tumoi	туре	. aurenai, Leu	kaemia, breast tumors		
	ation Route ure time <sup>.</sup> Type	: Mouse : Oral : 2 Years : 3,000 mg/kg : Lungs : Benign tumo	body weight or(s)		
Carcin ment	ogenicity - Assess-	: Weight of ev cinogen	Weight of evidence does not support classification as a cal		
Penro	ductive toxicity				
-	assified based on ava	ilable information			
	onents:				
ampic Effects	s on fertility	: Test Type: F Species: Gu Target Orga			
Effects ment	s on foetal develop-	Species: Ra Developmer	Development t ital Toxicity: NOAEL: 250 mg/kg body weight ffects on foetal development		

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.



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Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
ampio	cillin:		
	EL cation Route sure time	: Rat : 3,000 mg/kg : Oral : 13 Weeks : Diarrhoea	
	EL cation Route sure time	: Mouse : 2,000 mg/kg : Oral : 13 Weeks : Diarrhoea	
Expos	EL cation Route sure time et Organs	: Rat : 750 mg/kg : Oral : 2 yr : Thyroid, foresto : Diarrhoea, Saliv	omach vation, decreased activity
Expos	EL cation Route sure time et Organs	: Mouse : 2,000 mg/kg : Oral : 2 yr : forestomach : Ulceration, Infla	ammation, fungal infections

### Aspiration toxicity

Not classified based on available information.

## Experience with human exposure

# Components:

ampicillin:	
Inhalation	Symptoms: Asthma, Hay fever
	Remarks: May cause allergy or asthma symptoms or breath- ing difficulties if inhaled.
Ingestion	Symptoms: skin rash, Nausea, Diarrhoea, Vomiting, colitis, urticaria

## Section 12: Ecological information

# Ecotoxicity

### Components:

ampicillin:



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Toxic	sity to fish	:		ipes (Japanese medaka)): > 1,000 mg/l
			Exposure time: 9 LC50 (Oncorhyno Exposure time: 9	chus mykiss (rainbow trout)): > 100 mg/l
	ity to daphnia and other tic invertebrates	:	EC50 (Daphnia n Exposure time: 4	nagna (Water flea)): > 100 mg/l 8 h
	Toxicity to algae/aquatic plants		Exposure time: 7	flos-aquae): 190 μg/l 2 h est Guideline 201
			Exposure time: 7	a flos-aquae): 13 μg/l 2 h est Guideline 201
			mg/l Exposure time: 7	chneriella subcapitata (green algae)): > 100 2 h est Guideline 201
			mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 100 2 h est Guideline 201
	ctor (Acute aquatic tox-	:	1	
	icity) Toxicity to microorganisms		EC50: > 1,000 m Exposure time: 3 Test Type: Respi Method: OECD T	ĥ
			NOEC: 9 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
Pers	istence and degradabil	ity		
<u>Com</u>	ponents:			
-	cillin: egradability	:	Biodegradation: Exposure time: 2	35 %



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Biog	cumulative potential				
	-				
Comp	oonents:				
	<b>cillin:</b> on coefficient: n- ol/water	: log Pow: -2.0 pH: 7			
	l <b>ity in soil</b> Ita available				
	adverse effects ata available				
Section 13	3: Disposal considera	tions			
Dispo	osal methods				
-	e from residues		e of waste into sewer.		
Conta	Contaminated packaging : Emp dling		Dispose of in accordance with local regulations. 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	4: Transport informat	ion			
Interr	national Regulations				
UNR	ſDG	N La Cara an Para La La			

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



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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		
UN number	: Not applicable	
Proper shipping name	: Not applicable	
Class	: Not applicable	
Subsidiary risk	: Not applicable	
Packing group	: Not applicable	
Labels	: Not applicable	
Hazchem Code	: 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

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

#### **HSW Controls**

Certified handler certificate not required. Tracking hazardous substance not required. Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

#### 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/



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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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