

Version 4.0	Revision Date: 06.07.2024		9S Number: 73595-00017	Date of last issue: 06.04.2024 Date of first issue: 16.01.2018		
SECTION 1. IDENTIFICATION						
Produ	Product name		Amoxicillin Trihy	Amoxicillin Trihydrate Paste Formulation		
Manu	ifacturer or supplier's	s deta	ils			
Comp	Company		MSD	MSD		
Addre	Address		Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP			
Telep	hone	:	908-740-4000			
Emer	gency telephone	:	1-908-423-6000			
E-ma	il address	:	EHSDATASTEWARD@msd.com			
Reco	mmended use of the	chem	nical and restricti	ons on use		
Recommended use Restrictions on use		:	Veterinary product Not applicable			

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Respiratory 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
Hazard Statements	:	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 vapors. 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. 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
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Components

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	>= 0,25 -< 1

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	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
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	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
delayed		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



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m S fiç H	Unsuitable extinguishing : media Specific hazards during fire : fighting Hazardous combustion prod- : ucts		::	Carbon dioxide (CO2) Dry chemical None known. Exposure to combustion products may be a hazard to health. Carbon oxides				
00	ds	extinguishing meth-	:	cumstances and t Use water spray to Remove undamag so. Evacuate area.	measures that are appropriate to local cir- ne surrounding environment. cool unopened containers. Jed containers from fire area if it is safe to do , wear self-contained breathing apparatus.			
fo	or fire-f	ighters		Use personal prot				
SECTI	ION 6.	ACCIDENTAL RELE	ASE	EMEASURES				
tiv	ve equ	al precautions, protec- ipment and emer- rocedures	:		ective equipment. ng advice (see section 7) and personal ent recommendations (see section 8).			
E	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 ma 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 it employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regar certain local or national requirements.				

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	:	Avoid breathing vapors.
		Do not swallow.



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		Handle in accor practice, based assessment Keep container Already sensitiz to asthma, aller should consult t respiratory irrita	d or repeated contact with skin. dance with good industrial hygiene and safety on the results of the workplace exposure			
Conditions for safe storage		: Keep in properly Keep tightly close	/ labeled containers. sed.			
Materials to avoid		: Do not store wit	Store in accordance with the particular national regulations. 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			
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal		
	Further information	ation: RSEN				
Engineering measures	technologies t less quick cor All engineerin design and op protect produc	o control airborn inections). g controls should perated in accord cts, workers, and	controls and manufac le concentrations (e.g d be implemented by dance with GMP princ d the environment. require special contai	g., drip- facility siples to		
Personal protective equipment	nt					
Respiratory protection Filter type	exposure assorted recommended	essment demons d guidelines, use	ilation is not available strates exposures out respiratory protectio ganic vapor type	side the		
Hand protection Material	: Chemical-resi	Chemical-resistant gloves				
Eye protection	If the work en mists or aeros Wear a faces	vironment or act sols, wear the ap nield or other full	shields or goggles. ivity involves dusty co propriate goggles. face protection if the he face with dusts, m	re is a		
Skin and body protection Hygiene measures	: If exposure to		at. y during typical use, ety showers close to t			



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			Wash contaminat The effective oper engineering contr appropriate degov	ot eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, wning and decontamination procedures, monitoring, medical surveillance and the tive controls.
SECTI	ON 9. PHYSICAL AND CH	EMIC	CAL PROPERTIES	8
A	opearance	:	paste	
C	olor	:	colorless, to, whi	te
0	dor	:	characteristic	
0	dor Threshold	:	No data available	9
pł	4	:	No data available	9
М	elting point/freezing point	:	No data available	9
	itial boiling point and boiling nge	:	No data available	9
FI	ash point	:	No data available	9
E	vaporation rate	:	No data available	9
FI	ammability (solid, gas)	:	Not classified as	a flammability hazard
FI	ammability (liquids)	:	No data available	9
	pper explosion limit / Upper ammability limit	:	No data available	9
	ower explosion limit / Lower ammability limit	:	No data available	9
Va	apor pressure	:	No data available	9
R	elative vapor density	:	No data available	9
R	elative density	:	No data available	9
D	ensity	:	No data available	9
So	blubility(ies) Water solubility	:	slightly soluble	
	artition coefficient: n-	:	Not applicable	
	ctanol/water utoignition temperature	:	No data available	9



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Decon	nposition temperature	:	No data available	e
Viscosity Viscosity, kinematic		:	No data available	e
Explosive properties		:	Not explosive	
Oxidiz	Oxidizing properties		The substance o	r mixture is not classified as oxidizing.
Molec	Molecular weight		No data available	e
Particl Particl	e characteristics e 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.
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:

Amoxicillin Trihydrate:

Acute oral toxicity	:	LD50 (Rat): > 8.000 mg/kg
		LD50 (Mouse): > 10.000 mg/kg
		LD50 (Dog): > 3.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.



ersion 0	Revision Date: 06.07.2024		OS Number: 73595-00017	Date of last issue: 06.04.2024 Date of first issue: 16.01.2018		
Resp	iratory or skin sensi	itizatio	n			
Skin	sensitization					
Not c	assified based on ava	ailable	information.			
-	iratory sensitization					
-		na sym	ptoms or breath	ng difficulties if inhaled.		
	oonents:					
	cicillin Trihydrate:		0			
Resu Rema		:	Sensitizer May cause sens	sitization by inhalation.		
		·	largely based on human evidence			
Germ	cell mutagenicity					
Not c	assified based on ava	ailable	information.			
<u>Com</u>	oonents:					
Amo	cicillin Trihydrate:					
Geno	toxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative			
Genotoxicity in vivo :			Test Type: Micr Species: Mouse Result: negative	9		
			Test Type: Rod Species: Mouse Result: negative			
	nogenicity lassified based on ava	ailahle	information			
	oductive toxicity	unubic				
•	assified based on ava	ailable	information.			
<u>Com</u>	oonents:					
	kicillin Trihydrate:					
	s on fertility	:	Test Type: Ferti	ility		
			Species: Rat Application Rou	ite: Oral		
				L: 200 mg/kg body weight		
			Result: Reduce	d fertility		
			Remarks: Not c	lassified due to inconclusive data.		
			Test Type: Ferti	lity		
			Species: Rat Application Rou	ite: Oral		
			Fertility: LOAEL	.: 500 mg/kg body weight		
			Result: Reduce	d fertility lassified due to inconclusive data.		



ersion .0	Revision Date: 06.07.2024		OS Number: 73595-00017	Date of last issue: 06.04.2024 Date of first issue: 16.01.2018	
Effect	s on fetal development	:	Test Type: Devel Species: Rat Application Route Developmental T Result: No embry	e: Oral oxicity: NOAEL: >= 1.000 mg/kg body weight	
			Result: Some evi based on animal	e: Oral oxicity: LOAEL: 200 mg/kg body weight dence of adverse effects on development,	
			Result: Reduced weight gain.		
	-single exposure assified based on availa	blo	information		
STOT	-repeated exposure assified based on availa				
	oonents:				
-	cicillin Trihydrate:				
Rema	-	:	Not classified due	e to inconclusive data.	
Repe	ated dose toxicity				
<u>Com</u>	oonents:				
Amo	cicillin Trihydrate:				
Speci		:	Rat		
Applic	cation Route sure time	÷	Oral 6 Months		
Rema		:		verse effects were reported	
Speci	es	:	Dog		
Applic	cation Route	:	Oral		
	sure time	: 6 Months			
Rema	urks	: No significant adverse effects were reported			
Aspir	ation toxicity				
	· · · · · · · · · · · · · · · · · · ·				

Not classified based on available information.



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Ехр	erience with human exp	osi	ıre	
<u>Con</u>	nponents:			
Ame	oxicillin Trihydrate:			
Inge	estion	:	flatulence, skin	usea, Vomiting, Abdominal pain, Diarrhea, rash, Breathing difficulties produce an allergic reaction.
SECTIO	N 12. ECOLOGICAL INF	OR	MATION	
Eco	toxicity			
<u>Con</u>	nponents:			
Amo	oxicillin Trihydrate:			
Тохі	icity to fish	:	Exposure time	us auratus (goldfish)): 0,035 mg/l 96 h 9 Test Guideline 203
Toxi plan	icity to algae/aquatic its	:	NOEC (green a Exposure time	algae): 530 mg/l 72 h
			EC50 (Synech 0,0022 mg/l Exposure time	ococcus leopoliensis (blue-green algae)): 96 h
			NOEC (blue-gr Exposure time	een algae): 0,0057 mg/l 72 h
M-F icity	actor (Acute aquatic tox-)	:	100	
M-F toxic	actor (Chronic aquatic city)	:	1	
Pers	sistence and degradabil	lity		
<u>Con</u>	nponents:			
Ame	oxicillin Trihydrate:			
Bioc	degradability	:	Biodegradation Exposure time	28 d
			Method: OECE	Test Guideline 301B
Bioa	accumulative potential			
<u>Con</u>	nponents:			
Ame	oxicillin Trihydrate:			
Bioa	accumulation	:	Remarks: Bioa	ccumulation is unlikely.
	ition coefficient: n- Inol/water	:	log Pow: -0,12 Method: OECE	4 9 Test Guideline 107



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i ty in soil ta available						
adverse effects						
onents:						
icillin Trihydrate:						
s of PBT and vPvB sment	: Substance is not persistent, bioaccumulative, and toxic (PBT). Product does not contain substances which are very persis- tent and very bioaccumulative (vPvB) at levels of 0.1% or higher.					
13. DISPOSAL CONS	DERATIONS					
sal methods						
from residues	•	e of waste into sewer. accordance with local regulations.				
minated packaging	: Empty contain handling site	 Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. 				
	06.07.2024 ty in soil ta available adverse effects onents: icillin Trihydrate: s of PBT and vPvB sment I3. DISPOSAL CONS sal methods from residues	06.07.2024 2373595-00017 ty in soil aavailable adverse effects onents: icillin Trihydrate: s of PBT and vPvB s of PBT and vPvB : Substance is Product does tent and very higher. I3. DISPOSAL CONSIDERATIONS sal methods from residues : Do not dispos Dispose of in minated packaging				

International Regulations

UNRTDG UN number Proper shipping name	: UN 3082 : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
	N.O.S. (Amoxicillin Trihydrate)
	: 9 : III
Packing group Labels	. III : 9
Environmentally hazardous	yes
IATA-DGR	
UN/ID No.	: UN 3082
Proper shipping name	 Environmentally hazardous substance, liquid, n.o.s. (Amoxicillin Trihydrate)
Class	: 9
Packing group	
Labels	: Miscellaneous
Packing instruction (cargo aircraft)	: 964
Packing instruction (passen- ger aircraft)	: 964
Environmentally hazardous	: yes
IMDG-Code	
UN number	: UN 3082
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
	(Amoxicillin Trihydrate)
Class	: 9
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Version	Revision Date:		DS Number:	Date of last issue: 06.04.2024
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Labels EmS C Marine	pollutant	:	9 F-A, S-F yes	OL 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

The ingredients of this product are reported in the f	ollo	wing inventories:
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable
Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable

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

SECTION 16. OTHER INFORMATION

Revision Date	: (06.07.2024
Date format	: (dd.mm.yyyy

Further information

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Material Safety		eChem Portal search results and European Chemicals Agen-
Data Sheet		cy, http://echa.europa.eu/

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

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;



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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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