

Version 4.1	Revision Date: 28.09.2024		S Number: 00338-00020	Date of last issue: 06.07.2024 Date of first issue: 05.01.2017			
SECTION 1. IDENTIFICATION							
Produ	Product name		Amoxicillin Trihydrate Liquid Formulation				
Manu	afacturer or supplier's	s detai	ls				
Com	bany	:	MSD				
Addre	Address		Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP				
Telep	Telephone		908-740-4000				
Emer	Emergency telephone		1-908-423-6000				
E-ma	il address	: EHSDATASTEWARD@msd.com		/ARD@msd.com			
Reco	mmended use of the	chemi	ical and restriction	ons on use			
	mmended use ictions on use	:	Veterinary produ Not applicable	ict			

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Respiratory sensitization	Category 1	
Short-term (acute) aquatic hazard	Category 1	
Long-term (chronic) aquatic hazard	Category 2	
GHS label elements Hazard pictograms		
Signal Word	Danger	
Hazard Statements	H334 May cause allergy or asthma symptoms or breat difficulties if inhaled. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.	hing
Precautionary Statements	Prevention: P261 Avoid breathing mist or vapors. P273 Avoid release to the environment.	



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P284 Wear respiratory protection.

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

: Mixture

Substance / Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Coconut Oil	8001-31-8	>= 70 -< 90
Amoxicillin Trihydrate	61336-70-7	>= 10 -< 20
Fatty acids, C14-26, aluminum salts	97404-28-9	>= 1 -< 5

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
If inhaled	:	advice. 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
Notes to physician	:	when the potential for exposure exists (see section 8). Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES



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Suitable extinguishing media		:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical		
	Unsuita media	able extinguishing	:	None known.	
	Specific hazards during fire fighting		:	Exposure to comb	oustion products may be a hazard to health.
	Hazard ucts	lous combustion prod-	:	Carbon oxides Metal oxides	
	Specifi ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	•	l protective equipment fighters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.

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 protective 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 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.



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SECTION	I 7. HANDLING AND ST	ORAGE	
Loca	nical measures I/Total ventilation ce on safe handling	CONTROLS/ Use only with Do not breath Do not swallo Avoid contac Avoid prolong Handle in acc practice, base assessment Keep contain Already sens to asthma, al should consu	
Conc	litions for safe storage	 Keep in properly labeled containers. Keep tightly closed. Store in accordance with the particular national regulation 	
Mate			with the following product types:

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Coconut Oil	8001-31-8	CMP (Mist)	10 mg/m ³	AR OEL
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal
	Further inform	ation: RSEN		
Fatty acids, C14-26, aluminum salts	97404-28-9	TWA (Respirable particulate matter)	1 mg/m ³ (Aluminum)	ACGIH

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	t
Respiratory protection :	If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.



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Hand	er type protection terial	: Particulates type : Chemical-resista		
Eye pi	rotection	 Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditi mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is potential for direct contact to the face with dusts, mists, 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. 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	:	strong
Odor 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
Vapor pressure	:	No data available

SAFETY DATA SHEET



Amoxicillin Trihydrate Liquid Formulation

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	Relative vapor density		:	No data available	e
	Relativ	e density	:	No data available	9
	Density	/	:	0,99 - 1,10 g/l	
	Solubili Wat	ity(ies) er solubility	:	No data available	9
	Partition coefficient: n- octanol/water Autoignition temperature Decomposition temperature		:	Not applicable	
			:	No data available	9
			:	No data available	e
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizii	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	9
	Particle Particle	e characteristics e size	:	Not applicable	

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	::	Oxidizing agents

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact
		Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Coconut	Oil:
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Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg
Acute dermal toxicity	:	LD50 (Guinea pig): > 3.000 mg/kg



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			Remarks: Bas	ed on data from similar materials				
	cicillin Trihydrate: oral toxicity	:	LD50 (Rat): >	8.000 ma/ka				
	,, ,							
			LD50 (Mouse)	: > 10.000 mg/kg 3 000 ma/ka				
			(<u>_</u>	0.000				
Fatty	acids, C14-26, alum	inum	salts:					
Acute	oral toxicity	:	Method: OECI	nale): > 2.000 mg/kg D Test Guideline 423 ed on data from similar materials				
Acute	inhalation toxicity	:		: 4 h				
Not cl	corrosion/irritation lassified based on ava conents:	ailable	information.					
Сосо	nut Oil:							
Speci Resul	es	:	Rabbit No skin irritatio	on				
Fattv	acids, C14-26, alum	ninum salts:						
Speci		:		human epidermis (RhE)				
Metho Rema		:	OECD Test G Based on data	uideline 431 I from similar materials				
Speci Metho		:	reconstructed OECD Test G	human epidermis (RhE) uideline 439				
Rema	arks	:	Based on data	from similar materials				
Resul	lt	:	No skin irritatio	on				
	us eye damage/eye lassified based on ava							
<u>Comp</u>	oonents:							
Сосо	nut Oil:							
Speci Resul		:	Rabbit No eye irritatic	n				
Fatty		inum	a a lúa :					
ιαιιν	acids, C14-26, alum	mum	saits:					



rsion	Revision Date: 28.09.2024	SDS Number: 1200338-00020	Date of last issue: 06.07.2024 Date of first issue: 05.01.2017				
Result Metho Remai	d	: No eye irritation : OECD Test Gui : Based on data f					
Respi	ratory or skin sensi	tization					
	ensitization assified based on ava	ailable information.					
-	ratory sensitization ause allergy or asthm		ng difficulties if inhaled.				
Comp	onents:						
Test T	s of exposure es	: Maximization Te : Skin contact : Guinea pig : negative	est				
Amox	icillin Trihydrate:						
Result Remai	-		sitization by inhalation. n human evidence				
Fatty a	acids, C14-26, alum	um salts:					
Test T Routes Specie Metho Result Remai	s of exposure es d	 Skin contact Mouse OECD Test Gui negative 	de assay (LLNA) deline 429 irom similar materials				
	cell mutagenicity assified based on ava	ailable information.					
<u>Comp</u>	onents:						
Cocor	nut Oil:						
Genote	oxicity in vitro	: Test Type: Bact Result: negative	erial reverse mutation assay (AMES)				
Amox	icillin Trihydrate:						
Genote	oxicity in vitro	: Test Type: Bact Result: negative	erial reverse mutation assay (AMES)				
Genote	oxicity in vivo	: Test Type: Micro Species: Mouse Result: negative)				
		Test Type: Rod Species: Mouse Result: negative					



ersion 1	Revision Date: 28.09.2024	-	OS Number: 00338-00020	Date of last issue: 06.07.2024 Date of first issue: 05.01.2017
	aaida C11.20 alumin			
-	acids, C14-26, alumir coxicity in vitro	ium :	Test Type: Bac Method: OECD Result: negative	terial reverse mutation assay (AMES) Test Guideline 471 e ed on data from similar materials
			Method: OECD Result: negative	itro mammalian cell gene mutation test Test Guideline 476 e ed on data from similar materials
	nogenicity assified based on avail	lable	information.	
-	oductive toxicity assified based on avail	lable	information.	
Comp	oonents:			
Amox	cicillin Trihydrate:			
Effect	s on fertility	:	Result: Reduce	ute: Oral L: 200 mg/kg body weight
			Result: Reduce	ute: Oral _: 500 mg/kg body weight
Effect	s on fetal development	t:		
			Result: Some e based on anima	e ute: Oral Toxicity: LOAEL: 200 mg/kg body weight widence of adverse effects on development,



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			weight gain. Remarks: Not cl	assified due to inconclusive data.					
Fatty	Fatty acids, C14-26, aluminum salts:								
-	ts on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative Remarks: Based on data from similar materials						
Effect	Effects on fetal development		Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative Remarks: Based on data from similar materials						
	F-single exposure lassified based on availa	able	information.						
STOT	-repeated exposure								
Not c	lassified based on availa	able	information.						
Com	oonents:								
Amo	kicillin Trihydrate:								
Rema	arks	:	Not classified du	e to inconclusive data.					
Repe	ated dose toxicity								
Com	oonents:								
Amo	kicillin Trihydrate:								
Speci		:	Rat						
	cation Route sure time	:	Oral 6 Months						
Rema		:		lverse effects were reported					
Speci		:	Dog						
	cation Route sure time	:	Oral 6 Months						
Rema		:	••	lverse effects were reported					
Fattv	acids, C14-26, alumini	um	salts:						
Speci		:	Rat						
٨٠٠٠	nation Pouto	:	>= 1000 mg/kg						
	cation Route sure time	÷	Ingestion 42 Days						
Rema		:		rom similar materials					



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Aspir	ation toxicity			
Not cl	assified based on availa	ble	information.	
Expe	rience with human exp	osu	ire	
<u>Com</u>	oonents:			
Amo	cicillin Trihydrate:			
Inges	tion	:	flatulence, skin	isea, Vomiting, Abdominal pain, Diarrhea, rash, Breathing difficulties produce an allergic reaction.
ECTION	12. ECOLOGICAL INFO	ORN	IATION	
Ecoto	oxicity			
<u>Comp</u>	oonents:			
Amo	cicillin Trihydrate:			
Toxic	ity to fish	:	Exposure time:	s auratus (goldfish)): 0,035 mg/l 96 h Test Guideline 203
Toxic plants	ity to algae/aquatic	:	NOEC (green a Exposure time:	
			EC50 (Synecho 0,0022 mg/l Exposure time:	coccus leopoliensis (blue-green algae)): 96 h
			NOEC (blue-gre Exposure time:	een algae): 0,0057 mg/l 72 h
	ctor (Acute aquatic tox-	:	100	
icity) M-Fao toxicit	ctor (Chronic aquatic y)	:	1	
Persi	stence and degradabil	ity		
Com	oonents:			
Amo	cicillin Trihydrate:			
Biode	gradability	:	Result: Readily Biodegradation: Exposure time: Method: OECD	88 %
Fatty	acids, C14-26, alumini	um :	salts:	
-	gradability	:	Result: Readily Biodegradation: Exposure time: Method: OECD	81,2 %



Versio 4.1	Version Revision Date: 4.1 28.09.2024		S Number: 0338-00020	Date of last issue: 06.07.2024 Date of first issue: 05.01.2017			
E	Bioaccumulative potential						
<u>c</u>	Components:						
	Amoxicillin Trihydrate: Bioaccumulation	: 1	: Remarks: Bioaccumulation is unlikely.				
•	Partition coefficient: n- octanol/water		og Pow: -0,124 Method: OECD Te	est Guideline 107			
F	- Fatty acids, C14-26, alumin	um sa	alts:				
F	Partition coefficient: n- octanol/water	: 1	og Pow: > 7 Remarks: Calcula	tion			
١	Mobility in soil No data available Other adverse effects						
<u>c</u>	Components:						
F	Amoxicillin Trihydrate: Results of PBT and vPvB assessment	F t	Product does not	persistent, bioaccumulative, and toxic (PBT). contain substances which are very persis- ccumulative (vPvB) at levels of 0.1% or			

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 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
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Amoxicillin Trihydrate)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR UN/ID No. Proper shipping name	:	UN 3082 Environmentally hazardous substance, liquid, n.o.s.
Proper shipping name	•	Environmentally hazardous substance, liquid, n.o.s.



or

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			(Amoxicillin Trihy	rdrate)
Cla	Class Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft) Environmentally hazardous		9	
Pa			ÎII	
			Miscellaneous	
			964	
Pa			964	
			yes	
IM	DG-Code			
	UN number Proper shipping name		UN 3082	
Pro			ENVIRONMENT	ALLY HAZARDOUS SUBSTANCE, LIQUID,
			N.O.S.	
			(Amoxicillin Trihy	drate)
Cla	ISS	:	9	,
Pa	cking group	:	III	
Lal	pels	:	9	
Err	nS Code	:	F-A, S-F	
Ma	rine 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 environmer mixture	ntal regulations/legi	slatio	n specific for the substance
	Argentina. Carcinogenic Substar Registry.	:	Not applicable	
Control of precursors and essential chemicals for the preparation of drugs.				Not applicable
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



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	Sources of key data used to compile the Material Safety Data Sheet Full text of other abbreviation ACGIH AR OEL		:	: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen cy, http://echa.europa.eu/		
					eshold Limit Values (TLV) ational Exposure Limits	
		I / TWA L / CMP	:	8-hour, time-weig TLV (Threshold L	5	
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 Sys- tem; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and						

۱r h n 4 d 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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