

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
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#### **SECTION 1:** Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier		
Trade name	:	Amoxicillin Trihydrate (17.2%) Liquid Formulation
1.2 Relevant identified uses of t	the s	substance or mixture and uses advised against
Use of the Sub- stance/Mixture	:	Veterinary product
Recommended restrictions on use	:	Not applicable
1.3 Details of the supplier of the	e saf	ety data sheet
Company	:	MSD Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom
Telephone	:	+1-908-740-4000
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

## Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat- egory 2	H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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Haza	rd pictograms	:		*	73
Signa	al word	:	Danger		
Haza	rd statements	:	H334		ause allergy or asthma symptoms or breath- ficulties if inhaled.
			H410	-	oxic to aquatic life with long lasting effects.
Preca	autionary statements	:	Prevention	:	
			P273	Avoid	release to the environment.
			Response:		
			P304 + P34		INHALED: Remove person to fresh air and comfortable for breathing.
			P342 + P31		
			P391		t spillage.

Hazardous components which must be listed on the label:

Amoxicillin Trihydrate

#### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2.2 %

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	Resp. Sens. 1A; H334 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity):	>= 10 - < 20

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			100 M-Factor (Chronic aquatic toxicity): 1	
Benzyl	alcohol	100-51-6 202-859-9 603-057-00	Acute Tox. 4; H302 Acute Tox. 4; H332 -5 Eye Irrit. 2; H319	>= 1 - < 10

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

4.1 Description of first aid measur	res	6
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.
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).
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.
4.2 Most important symptoms and	d e	ffects, both acute and delayed
Risks	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
		Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac- tive airways dysfunction syndrome).
4.3 Indication of any immediate m Treatment	nec :	lical attention and special treatment needed Treat symptomatically and supportively.

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#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
5.2 Special hazards arising from t	he	e substance or mixture
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-	:	Carbon oxides
ucts		Metal oxides

#### 5.3 Advice for firefighters

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

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
<b>6.2 Environmental precautions</b> 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. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.



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		ment to keep ma be pumped, stor Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and	provide dyking or other appropriate contain- aterial from spreading. If dyked material can re recovered material in appropriate container. hing materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- ulations are applicable. I 15 of this SDS provide information regarding hational requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

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 mist or vapours.
5	Do not swallow.
	Avoid contact with eyes.
	Avoid prolonged or repeated contact with skin.
	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.
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. 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.
7.2 Conditions for safe storage,	including any incompatibilities
Requirements for storage	· Keen in properly labelled containers. Keen tightly closed

Requirements for storage areas and containers	:	Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types:



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			Strong oxidizing Gases	agents
•	f <b>ic end use(s)</b> ific use(s)	:	No data availabl	e

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Amoxicillin Trihy- drate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal
	Further inform	nation: RSEN		

#### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Glycerides, mixed decanoyl and oc- tanoyl	Workers	Inhalation	Long-term systemic effects	177.79 mg/m3
	Workers	Skin contact	Long-term systemic effects	25.21 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	43.84 mg/m3
	Consumers	Skin contact	Long-term systemic effects	12.61 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12.61 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic	4 mg/kg

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μ		-				effects	bw/day
		Consume	rs	Ingestion		Acute systemic effects	20 mg/kg bw/day
Predi	cted No Effect Co	oncentratio	on (PN	IEC):			
Subst	ance name		Envi	ronmental	Compart	ment	Value
Glyce	rides, mixed deca oyl	noyl and	Oral	(Secondar	y Poison	ing)	0.03 mg/kg food
Benzy	/l alcohol		Fres	h water			1 mg/l
			Marii	ne water			0.1 mg/l
			Inter	mittent use	/release		2.3 mg/l
			Sewa	age treatm	ent plant		39 mg/l
			Fres	h water see	diment		5.27 mg/kg
			Marii	ne sedimer	nt		0.527 mg/kg
			Soil				0.456 mg/kg

### 8.2 Exposure controls

#### **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

Eye/face 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.
Hand protection		
Material	:	Chemical-resistant gloves
Skin and body protection Respiratory protection	:	Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

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

#### 9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	<ul> <li>Aqueous solution</li> <li>white, cream</li> <li>No data available</li> <li>No data available</li> </ul>
рН	: No data available



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	Melting	point/freezing point	:	No data available	
		oiling point and boiling	:	No data available	9
	range Flash p	point	:	No data available	9
	Evapor	ation rate	:	No data available	9
	Flamm	ability (solid, gas)	:	Not applicable	
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	
	Vapour	pressure	:	No data available	9
	Relativ	e vapour density	:	No data available	9
	Relativ	e density	:	No data available	9
	Density	/	:	0.900 - 1.100 g/c	m <sup>3</sup>
	Solubil	ity(ies)			
		ter solubility n coefficient: n-	:	No data available Not applicable	2
	octano	l/water			
	Auto-Ig	nition temperature	:	No data available	3
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ity cosity, kinematic	:	No data available	9
		ive properties	:	Not explosive	
		ng properties	:		r mixture is not classified as oxidizing.
~ ~					5
9.2		n <b>formation</b> ability (liquids)	:	No data available	9
		llar weight		No data available	
		-	•		·
	Particle	e size	:	Not applicable	



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<ul> <li>10.1 Reactivity Not classified as a reactivity hazard.</li> <li>10.2 Chemical stability Stable under normal conditions.</li> <li>10.3 Possibility of hazardous reactions Hazardous reactions : Can react with strong oxidizing agents.</li> <li>10.4 Conditions to avoid Conditions to avoid : None known.</li> <li>10.5 Incompatible materials</li> </ul>
Stable under normal conditions.         10.3 Possibility of hazardous reactions         Hazardous reactions         Hazardous reactions         Conditions to avoid         Conditions to avoid         None known.
Hazardous reactions       : Can react with strong oxidizing agents. <b>10.4 Conditions to avoid</b> .         Conditions to avoid       : None known.
Hazardous reactions       : Can react with strong oxidizing agents. <b>10.4 Conditions to avoid</b> .         Conditions to avoid       : None known.
Conditions to avoid : None known.
10.5 Incompatible materials
•
Materials to avoid : Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.
SECTION 11: Toxicological information
11.1 Information on toxicological effects
Information on likely routes of : Inhalation exposure Skin contact Ingestion Eye contact
Acute toxicity
Not classified based on available information.

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

#### Components:

Amoxicillin Trihydrate:		
Acute oral toxicity	:	LD50 (Rat): > 8,000 mg/kg
		LD50 (Mouse): > 10,000 mg/kg
		LD50 (Dog): > 3,000 mg/kg

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### Π

#### Benzyl alcohol:

I	Acute oral toxicity	:	LD50 (Rat): 1,620 mg/kg
	Acute inhalation toxicity	:	LC50 (Rat): > 4.178 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

#### Benzyl alcohol:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation
i vesuit	. NO SKITTITIATION

#### Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

#### Benzyl alcohol:

Species : Method : Result :	Rabbit
Method :	OECD Test Guideline 405
Result :	Irritation to eyes, reversing within 21 days

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

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

#### Components:

#### Amoxicillin Trihydrate:

Result Remarks	:	Sensitiser
Remarks	:	May cause sensitisation by inhalation.
		largely based on human evidence

#### **Benzyl alcohol:**

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



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#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

Amoxicillin Trihydrate:		
Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative
		Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Result: negative
Benzyl alcohol:		
Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Benzyl alcohol:

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 103 weeks
Method	: OECD Test Guideline 451
Species Application Route Exposure time Method Result	: negative

#### **Reproductive toxicity**

Not classified based on available information.

#### **Components:**

#### Amoxicillin Trihydrate:

Effects on fertility

: Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 200 mg/kg body weight

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3.0 06.07.2024 Effects on foetal develop- ment		Result: Reduced fertility Remarks: Not classified due to inconclusive data. Test Type: Fertility Species: Rat Application Route: Oral Fertility: LOAEL: 500 mg/kg body weight Result: Reduced fertility Remarks: Not classified due to inconclusive data. Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: >= 1,000 mg/kg body weig Result: No embryo-foetal toxicity Test Type: Development Species: Mouse Application Route: Oral Developmental Toxicity: LOAEL: 200 mg/kg body weight Result: Some evidence of adverse effects on development,		
		Test Type: Deve Species: Rat Application Rout Developmental T Result: Reduced weight gain	assified due to inconclusive data. lopment	
Benz	yl alcohol:			
	ts on fertility	Species: Rat Application Rout Result: negative	ity/early embryonic development e: Ingestion I on data from similar materials	
Effec ment	ts on foetal develop-	: Test Type: Embr Species: Mouse Application Rout Result: negative	ryo-foetal development e: Ingestion	

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.



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Components: Amoxicillin Trihydrate: Remarks		: Not classified of	due to inconclusive data.		
-	ated dose toxicity ponents:				
Specie Applic	ation Route sure time	: Rat : Oral : 6 Months : No significant a	adverse effects were reported		
	ation Route sure time	: Dog : Oral : 6 Months : No significant :	adverse effects were reported		
Specie NOAE Applic	EL cation Route sure time	: Rat : 1.072 mg/l : inhalation (dus : 28 Days : OECD Test Gu			
Aspiration toxicity Not classified based on available information.					
_	ience with human exp ponents:	Josure			
Ingest	c <b>icillin Trihydrate:</b> ion	flatulence, skir	usea, Vomiting, Abdominal pain, Diarrhoea, rash, Breathing difficulties produce an allergic reaction.		
SECTION	12: Ecological info	rmation			

#### 12.1 Toxicity

#### Components:

#### Amoxicillin Trihydrate:

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 0.035 mg/l Exposure time: 96 h Method: OECD Test Guideline 203



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Toxicity to algae/aquatic plants		:	NOEC (green algae): 530 mg/l Exposure time: 72 h		
			EC50 (Synechoco 0.0022 mg/l Exposure time: 96	occus leopoliensis (blue-green algae)): ວັ h	
			NOEC (blue-gree Exposure time: 72	n algae): 0.0057 mg/l 2 h	
M-F icity	Factor (Acute aquatic tox- /)	:	100		
M-F toxi	Factor (Chronic aquatic city)	:	1		
Ber	nzyl alcohol:				
Тох	icity to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): 460 mg/l 5 h	
	icity to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD T		
Tox plai	icity to algae/aquatic hts	:	EC50 (Pseudokiro mg/l Exposure time: 72 Method: OECD T		
			NOEC (Pseudoki mg/l Exposure time: 72 Method: OECD T		
aqu	cicity to daphnia and other atic invertebrates (Chron- pxicity)		Exposure time: 2	magna (Water flea)	
12.2 Pei	sistence and degradabil	ity			
<u>Co</u>	nponents:				
Am	oxicillin Trihydrate:				
Bio	degradability	:	Result: Readily bi Biodegradation: Exposure time: 28 Method: OECD T	38 %	

### Benzyl alcohol:

Biodegradability

:

Result: Readily biodegradable.



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			Biodegradation: Exposure time: 14	
12.3 Bioac	cumulative potential			
Comp	onents:			
Amox	icillin Trihydrate:			
Bioaco	cumulation	:	Remarks: Bioacc	umulation is unlikely.
	on coefficient: n- bl/water	:	log Pow: -0.124 Method: OECD T	est Guideline 107
Partiti	<b>/l alcohol:</b> on coefficient: n-	:	log Pow: 1.05	
octano				
<b>12.4 Mobil</b> No da	<b>ity in soil</b> ta available			
12.5 Resu	ts of PBT and vPvB a	sse	ssment	
<u>Produ</u>	ict:			
Asses	sment	:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
<u>Comp</u>	onents:			
Amox	icillin Trihydrate:			
Asses	sment	:	: Substance is not persistent, bioaccumulative, and toxic (PBT) Product does not contain substances which are very persistent and very bioaccumulative (vPvB) at levels of 0. or higher.	
12.6 Other	adverse effects			
<u>Produ</u> Endoc tial	ict: rine disrupting poten-	: This substance/mixture does not contain components cor ered to have endocrine disrupting properties for environm according to UK REACH Article 57(f).		ocrine disrupting properties for environment

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product

Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes

:



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Conta	aminated packaging	Waste codes sh discussion with Do not dispose of Empty container dling site for rec	specific, but application specific. ould be assigned by the user, preferably in the waste disposal authorities. of waste into sewer. rs should be taken to an approved waste han- ycling or disposal. specified: Dispose of as unused product.

#### **SECTION 14: Transport information**

14.1 UN number			
ADN	:	UN 3082	
ADR	:	UN 3082	
RID	:	UN 3082	
IMDG	:	UN 3082	
ΙΑΤΑ	:	UN 3082	
14.2 UN proper shippi	ng name		
ADN	:	ENVIRONMENTALLY N.O.S. (Amoxicillin Trihydrate	Y HAZARDOUS SUBSTANCE, LIQUID,
ADR	:	ENVIRONMENTALLY N.O.S. (Amoxicillin Trihydrate	/ HAZARDOUS SUBSTANCE, LIQUID,
RID	:	ENVIRONMENTALLY N.O.S. (Amoxicillin Trihydrate	/ HAZARDOUS SUBSTANCE, LIQUID,
IMDG	:	ENVIRONMENTALLY N.O.S. (Amoxicillin Trihydrate	Y HAZARDOUS SUBSTANCE, LIQUID,
ΙΑΤΑ	:	Environmentally hazardous substance, liquid, n.o.s. (Amoxicillin Trihydrate)	
14.3 Transport hazard	class(es)		
		Class	Subsidiary risks
ADN	:	9	
ADR	:	9	
RID	:	9	
IMDG	:	9	
ΙΑΤΑ	:	9	
14.4 Packing group			
ADN			



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C F		g group cation Code Identification Number	: : :	III M6 90 9	
F C F L	Hazard _abels	g group cation Code Identification Number restriction code		III M6 90 9 (-)	
F C F		g group cation Code Identification Number	: : :	III M6 90 9	
F	MDG Packing ∟abels EmS Co		:	III 9 F-A, S-F	
F 2 F F	aircraft)	instruction (cargo instruction (LQ)		964 Y964 III Miscellaneous	
l, F F F	ATA (F Packing ger airc	instruction (LQ)	:	964 Y964 III Miscellaneous	
14.5 E	Enviro	nmental hazards			
E	ADR	mentally hazardous	:	yes	
F	RID	mentally hazardous	•	yes	
I	MDG	mentally hazardous pollutant	•	yes	
L	ATA (F	Passenger) mentally hazardous	:	yes	
	ATA (C Environ	Cargo) mentally hazardous	:	yes	



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#### 14.6 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.

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks

: Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restriction	s (Annex 17)	:	Number on list 3 Substance(s) or n here according to in the regulation, i use/purpose or th restriction. Please tions in correspon determine whether	riction for the fol- buld be considered: nixture(s) are listed their appearance irrespective of their e conditions of the e refer to the condi- iding Regulation to er an entry is appli- ng on the market or
UK REACH Candidate list of concern (SVHC) for Authoris		:	Not applicable	
The Persistent Organic Pollu Regulation (EU) 2019/1021 a ain)	tants Regulations (retained	:	Not applicable	
Regulation (EC) No 1005/20 plete the ozone layer	09 on substances that de-	:	Not applicable	
UK REACH List of substances subject to authorisation (Annex XIV)			Not applicable	
GB Export and import of haz Informed Consent (PIC) Reg		:	Not applicable	
Control of Major Accident Ha	zards Regulations 2015 (CC	DMA	λH)	
_			Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS		100 t	200 t

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

Aquatic Chronic

Eye Irrit.



### Amoxicillin Trihydrate (17.2%) Liquid Formulation

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			-	he following inventories:		
AICS	5	: r	not determined			
DSL		: r	not determined			
IECS	SC	: r	not determined			
	<b>15.2 Chemical safety assessment</b> A Chemical Safety Assessment has not been carried out.					
SECTIO	N 16: Other informa	tion				
Othe	er information	a		ges have been made to the previous version the body of this document by two vertical		
Full	text of H-Statements					
H30	2	: F	Harmful if swallow	ved.		
H31	-		Causes serious e			
H33			Harmful if inhaled			
H33	4		vlay cause allergy ies if inhaled.	or asthma symptoms or breathing difficul-		
H40	n		/ery toxic to aqua	tic life		
H41				itic life with long lasting effects.		
Full	text of other abbrevia	tions				
Acut	e Tox.	: A	Acute toxicity			
Aqua	atic Acute	: 5	Short-term (acute	) aquatic hazard		

Respiratory sensitisation Resp. Sens. : ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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;

Long-term (chronic) aquatic hazard

Eye irritation

:



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NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

#### Further information

Sources of key data used compile the Safety Data Sheet	eChem Po	hnical data, data from raw material SDSs, OECD tal search results and European Chemicals Agen- cha.europa.eu/
Classification of the mix	ture:	Classification procedure:
Resp. Sens. 1	H334	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 2	H411	Calculation method

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

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.

#### GB / EN