UK REACH Regulations SI 2019/758



Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.6	28.09.2024	10843712-00007	Date of first issue: 30.08.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Cloxacillin / Ampicillin Formulation

Other means of identification : Bovaclox Dry Cow (A004495)

1.2 Relevant identified uses of the 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 safety 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

Skin sensitisation, Category 1 Long-term (chronic) aquatic hazard, Category 3 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H317: May cause an allergic skin reaction. H412: Harmful 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)

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Hazard pictograms		:		
Sig	nal word	: C	Danger	
Haz	ard statements		H334 May o	ause an allergic skin reaction. ause allergy or asthma symptoms or breath- fficulties if inhaled.
		F		ful to aquatic life with long lasting effects.
Pre	cautionary statements	F F	P280 Wear Response: P304 + P340 IF keep	release to the environment. protective gloves. INHALED: Remove person to fresh air and comfortable for breathing.
		F	advice P342 + P311 If e POIS P362 + P364 Ta	skin irritation or rash occurs: Get medical e/ attention. experiencing respiratory symptoms: Call a ON CENTER/ doctor. ke off contaminated clothing and wash it e reuse.

Hazardous components which must be listed on the label: cloxacillin ampicillin

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative tive 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)
cloxacillin	61-72-3 200-514-7	Resp. Sens. 1; H334 Skin Sens. 1; H317	>= 10 - < 20
ampicillin	69-53-4 200-709-7	Resp. Sens. 1; H334 Aquatic Acute 1; H400 Aquatic Chronic 2;	>= 2.5 - < 10

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			H411 M-Factor (Acute aquatic toxicity): 1	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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.
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, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
effects, both acute and delayed
May cause an allergic skin reaction. 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, reactive airways dysfunction syndrome).
dical 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 the substance or mixture

J.2 Special hazalus ansing nom	une	
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Chlorine compounds Nitrogen oxides (NOx) Sulphur compounds Sulphur oxides 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).
6.2 Environmental precautions		
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).



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6.3 Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up with inert absorbent material.
	For large spills, provide dyking or other appropriate contain- ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent.
	Local or national regulations may apply to releases and dis-
	posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable.
	Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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	: Do not get on skin or clothing. Do not breathe vapours.
	Do not swallow.
	Avoid contact with eyes.
	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
	Keep container tightly closed.
	Already sensitised individuals, and those susceptible
	to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira- tory irritants or sensitisers.
	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. Contaminated work clothing should not be allowed out of the workplace. 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	:	Keep in properly labelled containers. Keep tightly closed.
areas and containers		Store in accordance with the particular national regulations.



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Advic	e on common storage	: No special res	strictions on storage with other products.
•	ic end use(s) fic use(s)	: No data availa	ble

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis		
cloxacillin	61-72-3	TWA	100 µg/m3 (OEB 2)	Internal		
	Further inform	Further information: RSEN, DSEN				
		Wipe limit	100 µg/100 cm2	Internal		
ampicillin	69-53-4	TWA	0.6 mg/m3 (OEB 2)	Internal		
	Further inform	nation: RSEN				

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.
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	: cream
Colour	: off-white



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	Odour Odour	Threshold	:	No data available No data available	
	рН		:	No data available	
	Melting	point/freezing point	:	No data available	
		oiling point and boiling	:	No data available	
	range Flash p	point	:	No data available)
	Evapor	ation rate	:	Not applicable	
	Flamm	ability (solid, gas)	:	No data available	9
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	Not applicable	
	Relativ	e vapour density	:	Not applicable	
	Relativ	e density	:	No data available)
	Density	/	:	No data available)
		er solubility n coefficient: n-	:	No data available Not applicable	
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance of	r mixture is not classified as oxidizing.
9.2	Other ir	formation			
	Flamm	ability (liquids)	:	No data available)
	Molecu	lar weight	:	No data available	
	Particle	e size	:	< 30 µm	

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SECTION 10: Stability and reactivity

10.1 Reactivity Not classified as a reactivity hazard. 10.2 Chemical stability Stable under normal conditions. 10.3 Possibility of hazardous reactions Hazardous reactions : None known. 10.4 Conditions to avoid Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : None.

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.

Components:

cloxacillin:		
Acute oral toxicity	:	LD50 (Rat): 5,000 mg/kg
		LD50 (Mouse): 5,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Mouse): 1,117 mg/kg Application Route: Intramuscular
		LD50 (Mouse): 916 mg/kg Application Route: Intravenous
		LD50 (Mouse): 1,500 mg/kg Application Route: Subcutaneous
		LD50 (Rat): 1,660 mg/kg Application Route: Intravenous



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			LD50 (Rat): 4,200 Application Route	
ampic	illin:			
-	oral toxicity	:	LD50 (Rat): 10,00	00 mg/kg
			LD50 (Mouse): 15	5,200 mg/kg
	toxicity (other routes of istration)	:	LD50 (Rat): 6,200 Application Route	
			LD50 (Mouse): 4, Application Route	
Skin d	corrosion/irritation			
Not cla	assified based on availa	ble	information.	
<u>Comp</u>	onents:			
cloxad	cillin:			
	rks	:	Not classified due	to lack of data.
Remain Seriou	us eye damage/eye irri	tati	on	
Serio Not cla				
Serio Not cla	u s eye damage/eye irri assified based on availa ponents: cillin:			to lack of data.
Seriou Not cla <u>Comp</u> cloxad Remai	u s eye damage/eye irri assified based on availa ponents: cillin:	ble :	information. Not classified due	to lack of data.
Seriou Not cla <u>Comp</u> cloxad Remai Respi Skin s	us eye damage/eye irri assified based on availa ponents: cillin: rks	ble : atic	information. Not classified due	to lack of data.
Seriou Not cla Comp cloxad Remai Respi Skin s May ca	us eye damage/eye irri assified based on availa conents: cillin: rks ratory or skin sensitis sensitisation	ble : atic	information. Not classified due	to lack of data.
Seriou Not cla Comp cloxad Remai Respi Skin s May ca Respi	us eye damage/eye irri assified based on availa conents: cillin: rks ratory or skin sensitis sensitisation ause an allergic skin rea	ble : actic	information. Not classified due on	
Seriou Not cla Comp cloxad Remai Respi Skin s May ca Respi May ca	us eye damage/eye irri assified based on availa conents: cillin: rks ratory or skin sensitis sensitisation ause an allergic skin rea ratory sensitisation	ble : actic	information. Not classified due on	
Seriou Not cla Comp cloxad Remai Respi Skin s May ca Respi May ca	us eye damage/eye irri assified based on availa conents: cillin: rks ratory or skin sensitis sensitisation ause an allergic skin rea ratory sensitisation ause allergy or asthma s conents:	ble : actic	information. Not classified due on	
Seriou Not cla Comp cloxad Remai Respi Skin s May ca Respi May ca Comp cloxad Expos	us eye damage/eye irri assified based on availa <u>conents:</u> cillin: rks ratory or skin sensitis sensitisation ause an allergic skin rea ratory sensitisation ause allergy or asthma conents: cillin: ure routes	ble : actic	information. Not classified due on on. nptoms or breathing Dermal	difficulties if inhaled.
Seriou Not cla Comp Cloxad Remai Respi Skin s May ca Respi May ca Comp cloxad	us eye damage/eye irri assified based on availa conents: cillin: rks ratory or skin sensitis sensitisation ause an allergic skin rea ratory sensitisation ause allergy or asthma s conents: cillin: ure routes sment	ble : actic	information. Not classified due on on. nptoms or breathing Dermal	
Seriou Not cla Comp Cloxad Remai Respi Skin s May ca Respi May ca Comp Cloxad Expos Asses	us eye damage/eye irri assified based on availa conents: cillin: rks ratory or skin sensitis sensitisation ause an allergic skin rea ratory sensitisation ause allergy or asthma s conents: cillin: ure routes sment	ble : actic	information. Not classified due on on. nptoms or breathing Dermal Probability or evic positive	difficulties if inhaled.
Seriou Not cla Comp Cloxad Remai Respi Skin s May ca Respi May ca Comp cloxad Expos Asses Result	us eye damage/eye irri assified based on availa conents: cillin: rks ratory or skin sensitist sensitisation ause an allergic skin rea ratory sensitisation ause allergy or asthma s conents: cillin: ure routes sment	ble : actic	information. Not classified due on on. Dermal Probability or evic positive Probability of resp	g difficulties if inhaled. lence of skin sensitisation in humans
Seriou Not cla Comp Cloxad Remai Respi Skin s May ca Respi May ca Comp cloxad Expos Asses Result Asses	us eye damage/eye irri assified based on availa conents: cillin: rks ratory or skin sensitis sensitisation ause an allergic skin rea ratory sensitisation ause allergy or asthma s conents: cillin: ure routes sment	ble : actic	information. Not classified due on on. Dermal Probability or evic positive Probability of resp animal testing	g difficulties if inhaled. lence of skin sensitisation in humans

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Result	t	:	Sensitiser	
Not cla	cell mutagenicity assified based on av ponents:	ailable	information.	
cloxa				
	toxicity in vitro	:	Result: negative	erial reverse mutation assay (AMES) ation given is based on data obtained from es.
Genot	toxicity in vivo	:	Test Type: Micro Species: Mouse Result: negative Remarks: Inform similar substance	ation given is based on data obtained from
ampio	cillin:			
•	toxicity in vitro	:	Test Type: Bacte Result: negative	erial reverse mutation assay (AMES)
				o mammalian cell gene mutation test use lymphoma cells
				chromatid exchange assay inese hamster ovary cells
				mosomal aberration inese hamster ovary cells
				mosomal aberration man lymphocytes
Genot	toxicity in vivo	:	Test Type: Micro Species: Rat Application Rout Result: negative	
	nogenicity assified based on av	ailable	information.	
Comp	oonents:	-		
cloxa				
/u				



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ampici	illin:			
Specie			Rat	
	ation Route	:	Oral	
		:	2 Years	
Exposi	ure time	•		
Tumor	Туре	:	750 mg/kg body adrenal, Leukaer	nia, breast tumors
Specie	c.		Mouse	
		•		
	ation Route		Oral	
Exposi	ure time	:	2 Years	
		:	3,000 mg/kg bod	y weight
Tumor	Туре	:	Lungs	
Remar	ks	:	Benign tumor(s)	
Carcino ment	ogenicity - Assess-	:	Weight of eviden cinogen	ce does not support classification as a car-
	ductive toxicity Issified based on avai	lable	information.	
Compo	onents:			
cloxac	illin			
Effects	on fertility	:	Test Type: Multi-	generation study
			Species: Rat	
			Application Route	
				500 mg/kg body weight
			Result: No effects	s on fertility, No effects on reproduction pa-
			rameters	
Effects	on foetal develop-	:	rameters Test Type: Devel	opment
Effects ment	on foetal develop-	:	Test Type: Devel	opment
	on foetal develop-	:	Test Type: Devel Species: Rabbit	
	on foetal develop-	:	Test Type: Devel Species: Rabbit Application Route	e: Oral
	on foetal develop-	:	Test Type: Devel Species: Rabbit Application Route Developmental T	
	on foetal develop-	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed.
	on foetal develop-	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed.
	on foetal develop-	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed. opment
	on foetal develop-	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route	e: Oral oxicity: NOAEL: 100 mg/kg body weight rmations were observed. opment e: Intramuscular
	on foetal develop-	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T	e: Oral oxicity: NOAEL: 100 mg/kg body weight rmations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight
	on foetal develop-	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T	e: Oral oxicity: NOAEL: 100 mg/kg body weight rmations were observed. opment e: Intramuscular
ment		:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T	e: Oral oxicity: NOAEL: 100 mg/kg body weight rmations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight
ment	illin:	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T Result: No effects	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight s on foetal development
ment		:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T Result: No effects Test Type: Fertilit	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight s on foetal development
ment	illin:	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T Result: No effects Test Type: Fertilit Species: Guinea	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight s on foetal development
ment ampici Effects	illin: on fertility	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T Result: No effects Test Type: Fertilit Species: Guinea Target Organs: L	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight s on foetal development
ment ampici Effects Effects	illin:	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T Result: No effects Test Type: Fertilit Species: Guinea Target Organs: L Test Type: Devel	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight s on foetal development
ment ampici Effects	illin: on fertility	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T Result: No effects Test Type: Fertilit Species: Guinea Target Organs: L Test Type: Devel Species: Rat	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight s on foetal development
ment ampici Effects Effects	illin: on fertility	:	Test Type: Devel Species: Rabbit Application Route Developmental T Result: No malfor Test Type: Devel Species: Rabbit Application Route Developmental T Result: No effects Test Type: Fertilit Species: Guinea Target Organs: L Test Type: Devel Species: Rat Developmental T	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed. opment e: Intramuscular oxicity: NOAEL: 250 mg/kg body weight s on foetal development

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STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

cloxacillin:		
Species	:	Rat
LÕAEL	:	7,000 mg/kg
Application Route	:	Intravenous
Exposure time	:	4 Weeks
Symptoms	:	Hypoglycemia

ampicillin:

Species	:	Rat
LOAEL	:	3,000 mg/kg
Application Route	:	Oral
Exposure time		13 Weeks
Symptoms	:	Diarrhoea
Species		Mouse
LOAEL		2,000 mg/kg
Application Route	:	Oral
• •		
Exposure time		13 Weeks
Symptoms		Diarrhoea
Species	:	Rat
LOAEL		750 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr
Target Organs	:	Thyroid, forestomach
	:	Diarrhoea, Salivation, decreased activity
Species		Mouse
LOAEL		2,000 mg/kg
Application Route		Oral
••	:	
Exposure time		2 yr
Target Organs		forestomach

Aspiration toxicity

Not classified based on available information.

:

Experience with human exposure

Components:

cloxacillin:

Symptoms

Inhalation

: Remarks: May cause sensitisation of susceptible persons.

Ulceration, Inflammation, fungal infections



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Skin contact		: Symptoms: Dermatitis Remarks: May irritate skin.				
Eye contact Ingestion		 Remarks: May irritate eyes. Symptoms: May cause, Gastrointestinal disturbance, Rash Remarks: May cause sensitisation of susceptible persons. 				
ampi	cillin:					
Inhala	ation	: Symptoms: As Remarks: May ing difficulties i	cause allergy or asthma symptoms or breath-			
Inges	tion		n rash, Nausea, Diarrhoea, Vomiting, colitis,			

SECTION 12: Ecological information

12.1 Toxicity

Components:		
ampicillin:		
Toxicity to fish		LC50 (Oryzias latipes (Japanese medaka)): > 1,000 mg/l Exposure time: 96 h
		LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Anabaena flos-aquae): 190 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae): 13 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic tox- icity)	:	1
Toxicity to microorganisms	:	EC50 : > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition

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

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		I	Vethod: OECD T	Test Guideline 209
		-	NOEC : 9 mg/l Exposure time: 3 Fest Type: Respi Method: OECD T	
12.2 Persi	istence and degradab	ility		
Com	oonents:			
ampi	cillin:			
-	gradability	l	Result: rapidly de Biodegradation: Exposure time: 2 Method: OECD T	35 %
12.3 Bioa	ccumulative potential			
<u>Com</u>	oonents:			
cloxa	cillin:			
	ion coefficient: n- ol/water	:	og Pow: 2.44	
ampi				
	ion coefficient: n- ol/water		og Pow: -2.0 oH: 7	
	lity in soil ata available			
12.5 Resu	llts of PBT and vPvB a	assess	ment	
Prod	uct:			
Asses	ssment	t	o be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Othe	r adverse effects			
Prod	uct:			
	crine disrupting poten-	(ered to have end	nixture does not contain components consid- locrine disrupting properties for environment REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods



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Produ	ict minated packaging	According to the are not product Waste codes sh discussion with Do not dispose	cordance with local regulations. European Waste Catalogue, Waste Codes 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-
Conta	ininateu packaging	dling site for rec	ycling or disposal. specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.4 Packing group		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good



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14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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 mix-ture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	Conditions of restrict lowing entries should Number on list 3	
	Substance(s) or mixt here according to the in the regulation, irre use/purpose or the c restriction. Please re tions in correspondin determine whether a cable to the placing o not.	ir appearance spective of their onditions of the fer to the condi- g Regulation to n entry is appli-
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	Not applicable	
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	Not applicable	
Regulation (EC) on substances that deplete the ozone layer	Not applicable	
UK REACH List of substances subject to authorisation (Annex XIV)	Not applicable	
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	Not applicable	
Control of Major Accident Hazards Regulations 2015 (CC Not applicable	IAH)	

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.

The components of this product are reported in the following inventories:					
AICS	:	not determined			
DSL	:	not determined			



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IECS	С	:	not determined		
15.2 Chemical safety assessment A Chemical Safety Assessment has not been carried out.					
SECTION 16: Other information					
Other	r information	:	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 H-Statements					
H317 H334		:	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.		
H400 H411		:	Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.		
Full text of other abbreviations					
Aqua	tic Acute tic Chronic . Sens. Sens.	:	Short-term (acute Long-term (chron Respiratory sensi Skin sensitisation	ic) aquatic hazard tisation	

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; 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;



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

Classification of the m	nixture:	Classification procedure:
Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method
Aquatic Chronic 3	H412	Calculation method

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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