according to the Globally Harmonized System



## **Cloxacillin / Ampicillin Formulation**

Vers 2.0	sion	Revision Date: 28.09.2024		S Number: 43369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022		
1. P	1. PRODUCT AND COMPANY IDENTIFICATION						
	Produc	t name	:	Cloxacillin / Ampi	cillin Formulation		
	Other n	neans of identification	:	Bovaclox Dry Co	w (A004495)		
	Manufa	acturer or supplier's d	letai	ls			
	Compa		:	MSD			
	Addres	S	:	Briahnager - Off I Wagholi - Pune -	Pune Nagar Road India  412 207		
	Teleph	one	:	+1-908-740-4000	)		
	Emerge	ency telephone number	· ː	+1-908-423-6000	)		
	E-mail	address	:	EHSDATASTEW	ARD@msd.com		
		mended use of the ch mended use	nemi	ical and restriction			
		tions on use	:	Not applicable			

#### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

#### **GHS Classification**

GHS label elements Hazard pictograms	:	
Long-term (chronic) aquatic hazard	:	Category 3
Short-term (acute) aquatic hazard	:	Category 2
Skin sensitisation	:	Category 1
Respiratory sensitisation	:	Category 1

Signal word



according to the Globally Harmonized System



### **Cloxacillin / Ampicillin Formulation**

Version 2.0	Revision Date: 28.09.2024	SDS Number: 10843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
Haza	rd statements	H334 May caus difficulties if inh H401 Toxic to a	
Preca	autionary statements	P260 Do not bu P271 Use only P272 Contamin the workplace. P273 Avoid rel P280 Wear pro	ntainer tightly closed. reathe vapours. outdoors or with adequate ventilation. nated work clothing should not be allowed out ease to the environment. otective gloves/ protective clothing. spiratory protection.
		P304 + P340 II keep comfortat P333 + P317 If P342 + P316 If gency medical	F ON SKIN: Wash with plenty of water. F INHALED: Remove person to fresh air and ole for breathing. f skin irritation or rash occurs: Get medical help f experiencing respiratory symptoms: Get eme help immediately. Take off contaminated clothing and wash it befo
		<b>Storage:</b> P403 Store in a	a well-ventilated place.
		Disposal:	of contents/ container to an approved waste

Other hazards which do not result in classification

None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture	Э	
Components		
Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	>= 70 - < 90
cloxacillin	61-72-3	>= 10 - < 20
ampicillin	69-53-4	>= 5 - < 10
Hydroxyaluminum distearate	300-92-5	>= 1 - < 5

#### 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.

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Version 2.0	Revision Date: 28.09.2024		0S Number: 843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
lf inh	If inhaled In case of skin contact		If breathing is diff	jive artificial respiration. icult, give oxygen.
In ca			<ul> <li>Get medical attention.</li> <li>In case of contact, immediately flush skin with soap and ple of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul>	
In ca	se of eye contact	:	Flush eyes with v	vater as a precaution.
lf swa	allowed	:	If swallowed, DO Get medical atter	ntion if irritation develops and persists. NOT induce vomiting. ntion if symptoms occur. oughly with water.
	important symptoms effects, both acute and /ed	:	May cause an all May cause allerg ties if inhaled. Excessive expose other respiratory	ergic skin reaction. y or asthma symptoms or breathing difficul- ure may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, reac-
Prote	ection of first-aiders	:	First Aid respond and use the reco	Inction syndrome). ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).
Note	s to physician	:		ically and supportively.
5. FIREFI	GHTING MEASURES			
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (0 Dry chemical	
Unsu medi	itable extinguishing a	:	None known.	
Spec fighti	ific hazards during fire- ng	:	Exposure to com	bustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides Chlorine compou Nitrogen oxides ( Sulphur compour Sulphur oxides Metal oxides	NOx)
Spec ods	ific extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.

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# Cloxacillin / Ampicillin Formulation

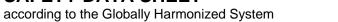
Version	Revision Date:	SDS Number:	Date of last issue: 05.12.2023
2.0	28.09.2024	10843369-00006	Date of first issue: 30.08.2022

#### 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 pro- tective 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 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.

#### 7. HANDLING AND STORAGE

Technical measures		See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation Advice on safe handling	:	
		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.
Conditions for safe storage	:	Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	No special restrictions on storage with other products.





## **Cloxacillin / Ampicillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 05.12.2023
2.0	28.09.2024	10843369-00006	Date of first issue: 30.08.2022

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m3	IN OEL
		STEL (Mist)	10 mg/m3	IN OEL
		TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH
cloxacillin	61-72-3	TWA	100 µg/m3 (OEB 2)	Internal
	Further inform	ation: RSEN, DS	SEN	
		Wipe limit	100 µg/100 cm2	Internal
ampicillin	69-53-4	TWA	0.6 mg/m3 (OEB 2)	Internal
	Further inform	ation: RSEN		
Hydroxyaluminum distearate	300-92-5	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	1 mg/m3 (Aluminium)	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 equipme	ent	
Respiratory protection Filter type Hand protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Combined particulates and organic vapour type
Material	:	Chemical-resistant gloves
Eye 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.

according to the Globally Harmonized System



# **Cloxacillin / Ampicillin Formulation**

Version 2.0	Revision Date: 28.09.2024	SDS Number: 10843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
Skin a	and body protection	: Work uniform or	laboratory coat.
Hygiene measures		flushing systems place. When using do r Contaminated w workplace. Wash contamina The effective op engineering cont appropriate dego	a emical is likely during typical use, provide eye a and safety showers close to the working not eat, drink or smoke. ork clothing should not be allowed out of the ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, e monitoring, medical surveillance and the ative controls.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	cream
Colour	:	off-white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		

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Version 2.0	Revision Date: 28.09.2024	-	S Number: 843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022		
	Water solubility	:	No data available	9		
	rtition coefficient: n- anol/water	:	Not applicable			
	to-ignition temperature	:	No data available	9		
De	composition temperature	:	No data available	9		
Vis	cosity Viscosity, kinematic	:	Not applicable			
Ex	plosive properties	:	Not explosive			
Ox	idizing properties	:	The substance o	r mixture is not classified as oxidizing.		
Мс	lecular weight	:	No data available	9		
	rticle characteristics rticle size	:	< 30 µm			
10. STA		ſ				
Ch Po tior	-	:	Stable under nor None known.	a reactivity hazard. mal conditions.		
Inc Ha	nditions to avoid compatible materials zardous decomposition oducts	:	None known. None. No hazardous de	ecomposition products are known.		
11. TO	11. TOXICOLOGICAL INFORMATION					
	ormation on likely routes of posure	:	Inhalation Skin contact Ingestion Eye contact			
	ute toxicity					
	t classified based on availa	ablei	intormation.			
	<u>mponents:</u> nite mineral oil (petroleun	n).				
	ute oral toxicity	n): :	LD50 (Rat): > 5,0	00 mg/kg		
Ac	ute inhalation toxicity	:	Exposure time: 4 Test atmosphere:	ĥ		
Ac	ute dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg		
			7/40			

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rsion )	Revision Date: 28.09.2024		9S Number: 843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022	
			Assessment: The toxicity	substance or mixture has no acute derma	
cloxa	cillin:				
Acute	oral toxicity	:	LD50 (Rat): 5,000	) mg/kg	
			LD50 (Mouse): 5,	000 mg/kg	
	toxicity (other routes of histration)	:	LD50 (Mouse): 1, Application Route		
			LD50 (Mouse): 91 Application Route		
			LD50 (Mouse): 1, Application Route		
			LD50 (Rat): 1,660 Application Route		
			LD50 (Rat): 4,200 Application Route		
ampio	cillin:				
Acute oral toxicity :		:	LD50 (Rat): 10,00	10 mg/kg	
			LD50 (Mouse): 15	5,200 mg/kg	
	toxicity (other routes of istration)	:	LD50 (Rat): 6,200 Application Route		
			LD50 (Mouse): 4,600 mg/kg Application Route: Intravenous		
Hydro	oxyaluminum distearat	e:			
	oral toxicity	:	LD50 (Rat, female Method: OECD T Remarks: Based		
Acute	inhalation toxicity	:	LC50 (Rat): > 5.1 Exposure time: 4 Test atmosphere: Method: OECD T	h dust/mist	
Not cl	corrosion/irritation assified based on availa	ble	information.		
	<u>oonents:</u>				
Speci	e mineral oil (petroleun es	ı):	Rabbit		
Resul		÷	No skin irritation		

according to the Globally Harmonized System



# **Cloxacillin / Ampicillin Formulation**

ersion .0	Revision Date: 28.09.2024	-	OS Number: 843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
cloxa	ncillin:		Not classified du	ie to lack of data.
Reina		-	Not classified du	ie lu lack ul uala.
Hydr	oxyaluminum distea	arate:		
Speci Metho Rema	od	:	OECD Test Guid	uman epidermis (RhE) deline 431 rom similar materials
Speci Metho Rema	od	:	OECD Test Guid	uman epidermis (RhE) deline 439 rom similar materials
Resu	lt	:	No skin irritation	
Com White Spec			Rabbit	
Resu	lt	:	No eye irritation	
cloxa Rema	acillin: arks	:	Not classified du	e to lack of data.
Hydr	oxyaluminum distea	arate:		
Speci Metho Rema	od	:	Bovine cornea OECD Test Guic Based on data fr	deline 437 rom similar materials
Resu	lt	:	No eye irritation	
Resp	iratory or skin sens	itisatio	on	
-	sensitisation cause an allergic skin	reaction	on.	
-	<b>iratory sensitisation</b> cause allergy or asthr		ptoms or breathir	ng difficulties if inhaled.
Com	ponents:			
White	e mineral oil (petrole	eum):		
Test Expo Spec Resu	sure routes ies	:	Buehler Test Skin contact Guinea pig negative	

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## **Cloxacillin / Ampicillin Formulation**

ersion 0	Revision Date: 28.09.2024		Number: 3369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
cloxa	acillin:			
Expo	sure routes	: D	ermal	
	ssment	: P	robability or ev	vidence of skin sensitisation in humans
Resu	lt	: р	ositive	
Asse	ssment			spiratory sensitisation in humans based on
	1		nimal testing	
Resu	IT	: р	ositive	
ampi	cillin:			
	sure routes	: Ir	halation	
Resu	lt	: S	ensitiser	
Hydr	oxyaluminum diste	arate:		
Test	-		ocal lymph nod	de assay (LLNA)
	sure routes		kin contact	
Spec	ies	: N	louse	
Meth	od	: C	ECD Test Gui	deline 429
Resu	lt	: negative		
Rema	arks	: B	ased on data f	rom similar materials
Com	lassified based on a ponents: e mineral oil (petro		ormation.	
	otoxicity in vitro	-	est Type: In vit	tro mammalian cell gene mutation test
Cent			esult: negative	
Geno	toxicity in vivo	C	ytogenetic ass	
			pecies: Mouse	
				te: Intraperitoneal injection
				Test Guideline 474
			esult: negative	
		R	emarks: Base	d on data from similar materials
cloxa	cillin:			
Geno	toxicity in vitro			erial reverse mutation assay (AMES)
			esult: negative	
				nation given is based on data obtained fron
		S	imilar substand	ces.
Geno	toxicity in vivo	: Т	est Type: Micr	onucleus test
	-		pecies: Mouse	
		R	esult: negative	)
11			-	nation given is based on data obtained from

ampicillin:

similar substances.

Remarks: Information given is based on data obtained from

according to the Globally Harmonized System



rsion	Revision Date: 28.09.2024	SDS Number: 10843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
Geno	toxicity in vitro	: Test Type: Bact Result: negative	erial reverse mutation assay (AMES
			ro mammalian cell gene mutation te buse lymphoma cells
			r chromatid exchange assay ninese hamster ovary cells
			omosomal aberration ninese hamster ovary cells
			omosomal aberration Iman lymphocytes
Geno	toxicity in vivo	: Test Type: Micro Species: Rat Application Rou Result: negative	te: Oral
II Hydro	oxyaluminum distea	rate:	
Geno	toxicity in vitro	Method: OECD Result: negative	erial reverse mutation assay (AMES Test Guideline 471 9 d on data from similar materials
		Method: OECD Result: negative	rro mammalian cell gene mutation te Test Guideline 476 e d on data from similar materials
<b>  </b> Coroi	nogonioity		
	nogenicity lassified based on ava	ailable information.	
<u>Com</u>	oonents:		
White	e mineral oil (petrole	um):	
Speci	es	: Rat	
	cation Route	: Ingestion	
Expos Resul	sure time It	: 24 Months : negative	
	cillin:		
Rema		: Not classified du	ue to lack of data.
ampio		. Det	
Speci		: Rat	

according to the Globally Harmonized System



ersion 0	Revision Date: 28.09.2024	SDS Number:Date of last issue10843369-00006Date of first issue	
Expos	cation Route sure time r Type	<ol> <li>Oral</li> <li>2 Years</li> <li>750 mg/kg body weight</li> <li>adrenal, Leukaemia, breast tumors</li> </ol>	
Expos	cation Route sure time r Type	<ul> <li>Mouse</li> <li>Oral</li> <li>2 Years</li> <li>3,000 mg/kg body weight</li> <li>Lungs</li> <li>Benign tumor(s)</li> </ul>	
Carcir ment	nogenicity - Assess-	: Weight of evidence does not suppor cinogen	t classification as a car-
Not cl	oductive toxicity assified based on avai		
	e mineral oil (petroleu s on fertility	: Test Type: One-generation reproduce Species: Rat Application Route: Skin contact Result: negative	ction toxicity study
Effect ment	s on foetal develop-	: Test Type: Embryo-foetal developm Species: Rat Application Route: Ingestion Result: negative	ent
cloxa Effect	<b>cillin:</b> s on fertility	: Test Type: Multi-generation study Species: Rat Application Route: Oral Fertility: NOAEL: 500 mg/kg body w Result: No effects on fertility, No effer rameters	
Effect ment	s on foetal develop-	: Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 10 Result: No malformations were obse	
		Test Type: Development Species: Rabbit Application Route: Intramuscular Developmental Toxicity: NOAEL: 25 Result: No effects on foetal develop	

according to the Globally Harmonized System



### **Cloxacillin / Ampicillin Formulation**

Version 2.0	Revision Date: 28.09.2024		DS Number: 0843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
Effect	s on fertility	:	Test Type: Fertilit Species: Guinea Target Organs: U	
Effect ment	s on foetal develop-	:		opment oxicity: NOAEL: 250 mg/kg body weight s on foetal development
Hydro	oxyaluminum disteara	te:		
Effect	s on fertility	:	Species: Rat Application Route Method: OECD T Result: negative	eneration reproduction toxicity study e: Ingestion est Guideline 416 on data from similar materials
Effect ment	s on foetal develop-	:	Species: Rat Application Route Method: OECD T Result: negative	peneration reproduction toxicity study e: Ingestion fest Guideline 416 on data from similar materials

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.

#### Repeated dose toxicity

#### **Components:**

#### White mineral oil (petroleum):

Species LOAEL Application Route Exposure time		Rat 160 mg/kg Ingestion 90 Days
Species LOAEL Application Route Exposure time Method	:	Rat >= 1 mg/l inhalation (dust/mist/fume) 4 Weeks OECD Test Guideline 412
cloxacillin:		
Species LOAEL Application Route Exposure time Symptoms	:	Rat 7,000 mg/kg Intravenous 4 Weeks Hypoglycemia

according to the Globally Harmonized System



Version 2.0	Revision Date: 28.09.2024	SDS Number: 10843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
Spec LOAE Appli Expo Symp	EL cation Route sure time otoms ies	: Rat : 3,000 mg/kg : Oral : 13 Weeks : Diarrhoea : Mouse	
Expo	EL cation Route sure time ptoms	: 2,000 mg/kg : Oral : 13 Weeks : Diarrhoea	
Expo Targe		: Rat : 750 mg/kg : Oral : 2 yr : Thyroid, foresto : Diarrhoea, Saliv	mach ation, decreased activity
Expo Targe		: Mouse : 2,000 mg/kg : Oral : 2 yr : forestomach : Ulceration, Infla	mmation, fungal infections
Not c Expe	ration toxicity classified based on ava crience with human e		
	ponents: acillin:		
Inhala Skin	ation contact	: Remarks: May o : Symptoms: Der Remarks: May i	
Eye o Inges	contact stion	: Remarks: May i : Symptoms: May	
ampi	cillin:		
Inhal		: Symptoms: Asth Remarks: May o ing difficulties if	ause allergy or asthma symptoms or breath-
Ingos	stion		read Neuros Diarrhage Versiting colitie

according to the Globally Harmonized System



# Cloxacillin / Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05.12.2023
2.0	28.09.2024	10843369-00006	Date of first issue: 30.08.2022

#### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

#### Components:

White mineral oil (petroleum Toxicity to fish	<b>i):</b>	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	NOEC ( Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic tox- icity)	:	NOEC: 1,000 mg/l Exposure time: 28 d Species: Oncorhynchus mykiss (rainbow trout)
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC: 1,000 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
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

according to the Globally Harmonized System



Revision Date: 28.09.2024			Date of last issue: 05.12.2023 Date of first issue: 30.08.2022	
		Exposure time: 7 Method: OECD T	2 h Fest Guideline 201	
ctor (Acute aquatic tox-	:	1		
Toxicity to microorganisms		EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209		
		NOEC: 9 mg/l Exposure time: 3 Test Type: Respi Method: OECD T		
oxyaluminum distearat	e:			
•••		No toxicity at the	limit of solubility	
istence and degradabil	ity			
ponents:				
e mineral oil (petroleun	า):			
egradability	:	Result: Not readi Biodegradation: Exposure time: 2		
cillin:				
egradability	:	Result: rapidly de Biodegradation: Exposure time: 2 Method: OECD T	35 %	
oxyaluminum distearat	e:			
egradability	:	Result: Readily b Remarks: Based	iodegradable. on data from similar materials	
ccumulative potential				
ponents:				
acillin:				
tion coefficient: n- nol/water	:	log Pow: 2.44		
<b>cillin:</b> tion coefficient: n- nol/water	:	log Pow: -2.0 pH: 7		
	28.09.2024 actor (Acute aquatic tox- sity to microorganisms oxyaluminum distearat oxicology Assessment nic aquatic toxicity istence and degradabili ponents: e mineral oil (petroleun egradability icillin: egradability icillin: egradability ccumulative potential ponents: acillin: tion coefficient: n- hol/water	28.09.2024       10         actor (Acute aquatic tox-       :         bity to microorganisms       :         oxyaluminum distearate:       :         oxicology Assessment       :         nic aquatic toxicity       :         istence and degradability       :         ponents:       :         e mineral oil (petroleum):       :         egradability       :         icillin:       :         egradability       :         oxyaluminum distearate:       :         egradability       :         icillin:       :         icillin:       :         ion coefficient: n-       :         icillin:       :         icino:       :         icillin:       :         icino coefficient: n-       :	28.09.2024       10843369-00006         Exposure time: 7       Method: OECD 1         actor (Acute aquatic tox-       :       1         sity to microorganisms       :       EC50: > 1,000 m         Exposure time: 3       Test Type: Resp         Method: OECD 1       NOEC: 9 mg/l         NOEC: 9 mg/l       Exposure time: 3         Test Type: Resp       Method: OECD 1         oxyaluminum distearate:       NOEC: 9 mg/l         oxicology Assessment       No toxicity at the         nic aquatic toxicity       :         nic aquatic toxicity       :         e mineral oil (petroleum):       Result: Not readi         agradability       :         ponents:       :         e gradability       :         egradability       :         egradability       :         icillin:       :         egradability       :         oxyaluminum distearate:       :         egradability       :         icin coefficient: n-       :         hol/water       :         icin coefficient: n-       :         icin coefficient: n-       :         icin coefficient: n-       :	

according to the Globally Harmonized System



# **Cloxacillin / Ampicillin Formulation**

Version 2.0	Revision Date: 28.09.2024	SDS Number: 10843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022
II			
Hydr	oxyaluminum distear	ate:	
	tion coefficient: n- nol/water	: log Pow: 15.088 Remarks: Calcu	
	i <b>lity in soil</b> ata available		
Othe	r adverse effects		
No d	ata available		
13. DISPO	DSAL CONSIDERATION	DNS	
Disp	osal methods		
Wast	e from residues		of waste into sewer.
Cont	aminated packaging	: Empty container dling site for rec	cordance with local regulations. s should be taken to an approved waste han- ycling or disposal. specified: Dispose of as unused product.
4. TRAN	SPORT INFORMATIC	N	
Inter	national Regulations		
<b>UNR</b> Not r	<b>TDG</b> egulated as a dangero	us good	
	-DGR egulated as a dangero	us good	
	<b>3-Code</b> egulated as a dangero	us good	
	sport in bulk accordin applicable for product a	ng to IMO instruments s supplied.	5
-	ial precautions for us	ser	
15. REGL	ILATORY INFORMAT	ION	
Safe ture	ty, health and enviror	mental regulations/le	gislation specific for the substance or mix
	•	roduct are reported in : not determined	the following inventories:
AICS			
AICS DSL		: not determined	

#### **16. OTHER INFORMATION**

according to the Globally Harmonized System



#### **Cloxacillin / Ampicillin Formulation**

Version 2.0	Revision Date: 28.09.2024		DS Number: 843369-00006	Date of last issue: 05.12.2023 Date of first issue: 30.08.2022		
Revisio	on Date	:	28.09.2024			
Furthe	er information					
	compile the Safety Data		Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, 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.						
Date fo	ormat	:	dd.mm.yyyy			
Full text of other abbreviations						
ACGIH IN OEL	-	:		eshold Limit Values (TLV) levels of certain chemical substances in t.		

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be

according to the Globally Harmonized System



### **Cloxacillin / Ampicillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 05.12.2023
2.0	28.09.2024	10843369-00006	Date of first issue: 30.08.2022

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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