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

1.1	Product identifier Trade name	:	Gentamicin / Cloxacillin Formulation
1.2	Relevant identified uses of th	he 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	saf	ety data sheet
	Company	:	MSD Kilsheelan Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	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)

Respiratory sensitisation, Category 1

Skin sensitisation, Category 1 Reproductive toxicity, Category 1A Short-term (acute) aquatic hazard, 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.H360D: May damage the unborn child.H400: Very toxic to aquatic life.

H412: Harmful to aquatic life with long lasting effects.

### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms





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Signal	word	: [	Danger	
Hazard statements		H C H	H334 May caus difficulties if inhale H360D May dama	e an allergic skin reaction. e allergy or asthma symptoms or breathing ed. age the unborn child. c to aquatic life with long lasting effects.
Precautionary statements		F F F	P273 Avoid rele	ecial instructions before use. ease to the environment. tective gloves/ protective clothing/ eye protec- on.
		F F F	keep comfortable	experiencing respiratory symptoms: Call a R/ doctor.

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

### 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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

### 3.2 Mixtures

### Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
cloxacillin	61-72-3	Resp. Sens. 1;	2,2
	200-514-7	H334	
		Skin Sens. 1; H317	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

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Genta	amicin	1403-66-3 215-765-8	Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	0,5

For explanation of abbreviations see section 16.

# **SECTION 4: First aid measures**

## 4.1 Description of first aid measures

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	:	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.
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. Rinse mouth thoroughly with water.
4.2 Most important symptoms and	d e	ffects, both acute and delayed



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			May damage the	unborn child.
			other respiratory	ure may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, reac- unction syndrome).
4.3 Indi	cation of any immediate	me	dical attention and	d special treatment needed
Tre	eatment	:	Treat symptomat	ically and supportively.
SECTI	ON 5: Firefighting mea	sur	es	
5.1 Ext	inguishing media			
Suitable extinguishing media		:	Water spray Alcohol-resistant Carbon dioxide (0 Dry chemical	
Unsuitable extinguishing media		:	None known.	
5.2 Spe	cial hazards arising fron	n the	e substance or mi	ixture
	ecific hazards during fire- hting	:	Exposure to com	bustion products may be a hazard to health.
Ha uci	zardous combustion prod- s	• :	Carbon oxides Chlorine compou Nitrogen oxides ( Sulphur compour	NOx)
5.3 Adv	vice for firefighters			
	ecial protective equipment firefighters	t :		e, wear self-contained breathing apparatus. tective equipment.
Sp od	ecific extinguishing meth- s	:	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

### 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).



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6.2 Enviro	6.2 Environmental precautions								
	nmental precautions	<ul> <li>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.</li> </ul>							
Methods for cleaning up		For large spills, p ment to keep ma be pumped, stor Clean up remain bent. Local or national posal of this mat employed in the mine which regu Sections 13 and	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	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe mist or 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 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
Hygiene measures	:	environment. 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.



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		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 Con	ditions for safe storage,	incl	uding any incom	patibilities		
Requirements for storage : areas and containers		:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.			
Advice on common storage :		:	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases			
-	c <b>ific end use(s)</b> ecific use(s)	:	No data available			

# **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 inforn	Further information: RSEN, DSEN						
		Wipe limit 100 µg/100 cm2 Internal						
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB 2)	Internal				
	Further information: OTO							

### 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

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or	Eye/face protection	•
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Hand protection		aerosols.					
Material		: Chemical-resistant gloves					
Skin a	and body protection ratory protection	: Work uniform : If adequate loc sure assessme ommended gu	or laboratory coat. cal exhaust ventilation is not available or expo- ent demonstrates exposures outside the rec- idelines, use respiratory protection. buld conform to NS EN 14387				
Fil	ter type		ticulates and organic vapour type (A-P)				

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

## 9.1 Information on basic physical and chemical properties

Physical state	:	suspension
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Solubility(ies) Water solubility	:	No data available

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	ion coefficient: n- ol/water	: Not applicabl	e				
Vapo	ur pressure	: No data avail	: No data available				
Relat	ive density	: No data available					
Dens	ity	: No data available					
Relat	ive vapour density	: No data avail	able				
	cle characteristics article size	: Not applicabl	e				
9.2 Other	information						
Explo	osives	: Not explosive					
Oxidi	zing properties	: The substand	e or mixture is not classified as oxidizing.				
Evap	oration rate	: No data avail	able				
SECTION	N 10: Stability and I	eactivity					

## SECTION TO: 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 : Can react with strong oxidizing agents. 10.4 Conditions to avoid 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of	:	Inhalation
exposure		Skin contact

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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			Ingestion Eye contact	
	e <b>toxicity</b> assified based on availa	ble	information.	
Comp	oonents:			
cloxa	cillin:			
Acute	oral toxicity	:	LD50 (Rat): 5.000	) mg/kg
			LD50 (Mouse): 5.0	000 mg/kg
	toxicity (other routes of istration)	:	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	
Genta	amicin:			
Acute	oral toxicity	:	LD50 (Rat): 8.000	) - 10.000 mg/kg
			LD50 (Mouse): 10	).000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 0,2 Exposure time: 4 Test atmosphere: Remarks: No mor	h
	toxicity (other routes of istration)	:	LD50 (Rat): 67 - 9 Application Route	
			LD50 (Rat): 371 - Application Route	
			LDLo (Monkey): 3 Application Route	0 0

## Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

#### cloxacillin:

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Rem	narks	: Not classified due to lack of data.	
<b>Gen</b> Spec Resi		: Rabbit : Mild skin irritation	
	ous eye damage/eye classified based on ava		
Con	nponents:		
	a <b>cillin:</b> narks	: Not classified due to lack of data.	
<b>Gen</b> Spec Resi		: Rabbit : Mild eye irritation	
Res	piratory or skin sens	sation	
Skin	sensitisation		
May	cause an allergic skin	eaction.	
	piratory sensitisation		
Мау	cause allergy or asthr	a symptoms or breathing difficulties if inhaled.	
Con	ponents:		
clox	acillin:		
-	osure routes essment ult	<ul> <li>Dermal</li> <li>Probability or evidence of skin sensitisation in humans</li> <li>positive</li> </ul>	5
Asse	essment	: Probability of respiratory sensitisation in humans base animal testing	d on
Res	ult	: positive	
Gen	tamicin:		
Rem	narks	: No data available	
	m cell mutagenicity classified based on ava	lable information.	
Com	<u>iponents:</u>		
clox	acillin:		
Gen	otoxicity in vitro	<ul> <li>Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Information given is based on data obtained similar substances.</li> </ul>	l from



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G	Senoto	xicity in vivo	:	Test Type: Micron Species: Mouse Result: negative Remarks: Informa similar substances	tion given is based on data obtained from
G	entan	nicin:			
		xicity in vitro	:	Test Type: In vitro Result: negative	mammalian cell gene mutation test
				Test Type: Chrom Result: equivocal	osome aberration test in vitro
G	Genoto	xicity in vivo	:	cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo ) : Intravenous injection
Ν	lot clas	ogenicity ssified based on availa nents:	ble	information.	
cl	loxaci	llin:			
R	lemark	S	:	Not classified due	to lack of data.
G	entan	nicin.			
С		genicity - Assess-	:	No data available	
	•	luctive toxicity mage the unborn child			
<u>C</u>	ompo	onents:			
cl	loxaci	llin:			
E	ffects	on fertility	:		
	ffects nent	on foetal develop-	:		
				Test Type: Develo	opment

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		Species: Rabbit Application Route: Intramuscular Developmental Toxicity: NOAEL: 250 mg/kg body weight Result: No effects on foetal development
Genta	amicin:	
Effect	s on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Fertility: NOAEL: 20 mg/kg body weight Result: No significant adverse effects were reported
Effect ment	s on foetal develop-	<ul> <li>Test Type: Embryo-foetal development Species: Rabbit Developmental Toxicity: NOAEL: 3,6 mg/kg body weight Result: No embryo-foetal toxicity</li> </ul>
		Test Type: Embryo-foetal development Species: Rat Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 75 mg/kg body weight Result: Embryo-foetal toxicity
		Test Type: Embryo-foetal development Species: Mouse Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: foetal mortality, No malformations were observed.
		Test Type: Embryo-foetal development Species: Rat Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 50 mg/kg body weight Result: foetal mortality, No malformations were observed.
Repro sessn	oductive toxicity - As- nent	: Positive evidence of adverse effects on development from human epidemiological studies.
	- single exposure lassified based on avail	able information.
	- repeated exposure lassified based on avail	able information.
	oonents:	
Genta	amicin:	
	et Organs ssment	<ul> <li>Kidney, inner ear</li> <li>Causes damage to organs through prolonged or repeated exposure.</li> </ul>

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Repe	ated dose toxicity		
<u>Com</u>	ponents:		
cloxa	cillin:		
	EL cation Route sure time	: Rat : 7.000 mg/kg : Intravenous : 4 Weeks : Hypoglycemia	
Genta	amicin:		
Expo	EL cation Route sure time et Organs	: Dog : 3 mg/kg : Intramuscular : 12 Months : Kidney : Vomiting, Saliva	ation
Expos		: Monkey : 50 mg/kg : Subcutaneous : 3 Weeks : Kidney, inner e	ar
Expo		: Monkey : 6 mg/kg : Intramuscular : 3 Weeks : Blood, Kidney,	inner ear, Liver
Expos	ΞL	: Rat : 5 mg/kg : 10 mg/kg : Intramuscular : 52 Weeks : Kidney, Blood	
Expos	ΞL	: Rat : 12,5 mg/kg : 50 mg/kg : Intramuscular : 13 Weeks : Kidney	

Not classified based on available information.

# 11.2 Information on other hazards

#### Endocrine disrupting properties

#### Product:



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Asse	Assessment		The substance/mixture does not contain components consid ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 a levels of 0.1% or higher.		
Expe	erience with human ex	posure			
<u>Com</u>	ponents:				
cloxa	acillin:				
Inhal	ation	: Remarks: May cause sensitisation of susceptible perso			
Skin	contact		oms: Derm		
Evo (	contact		ˈks: May irri ˈks: May irri		
Inges		: Sympt	<ul> <li>Remarks: May irritate eyes.</li> <li>Symptoms: May cause, Gastrointestinal disturbance, Rash Remarks: May cause sensitisation of susceptible persons.</li> </ul>		
Gent	amicin:				
Inges	stion	Target			

# **SECTION 12: Ecological information**

### 12.1 Toxicity

### **Components:**

Gentamicin:	
Toxicity to daphnia and other : aquatic invertebrates	EC50 (Daphnia magna (Water flea)): 86 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
	LC50 (Americamysis): 30 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035
Toxicity to algae/aquatic : plants	EC50 (Pseudokirchneriella subcapitata (green algae)): 10 μg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (Pseudokirchneriella subcapitata (green algae)): 1,5 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
	EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 μg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l



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			Exposure time: 7 Method: OECD T	2 h Test Guideline 201
M-Fa icity)	ctor (Acute aquatic tox-	:	100	
Toxic	ity to microorganisms	:	Exposure time: 3 Test Type: Respi	h
M-Fa toxici	ctor (Chronic aquatic ty)	:	1	
12.2 Pers	istence and degradabi	lity		
Com	ponents:			
Gent	amicin:			
Biode	egradability	:	Result: rapidly de Biodegradation: Exposure time: 2 Method: OECD T	100 %
12.3 Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	acillin: ion coefficient: n- nol/water	:	log Pow: 2,44	
Partit	<b>amicin:</b> ion coefficient: n- nol/water	:	log Pow: < -2	
	<b>ility in soil</b> ata available			
12.5 Resu	Its of PBT and vPvB a	sse	ssment	
Prod	uct:			
Asse	ssment	:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Endo	ocrine disrupting prope	ertie	S	
Prod	uct:			
	ssment	:	ered to have end REACH Article 5	ixture does not contain components consid- ocrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at



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levels of 0.1% or higher.

## 12.7 Other adverse effects

No data available

## **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 are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

## **SECTION 14: Transport information**

### 14.1 UN number or ID number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
ΙΑΤΑ	:	UN 3082
14.2 UN proper shipping name		
ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
ΙΑΤΑ	:	Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
1/1 3 Transport bazard class(es)		

#### 14.3 Transport hazard class(es)

Class

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ADN		:	9	
ADR		:	9	
RID		:	9	
IMD	G	:	9	
ΙΑΤΑ	۱.	:	9	
14.4 Pac	king group			
Clas	ing group sification Code ard Identification Number	:	III M6 90 9	
ADR Pack Clas Haza Labe	ing group sification Code ard Identification Number		III M6 90 9 (-)	
Clas	ting group sification Code ard Identification Number els	:	III M6 90 9	
Labe	king group	:	III 9 F-A, S-F	
Pack aircr Pack	ting instruction (LQ)	:	964 Y964 III Miscellaneous	
Pack ger a Pack	A (Passenger) ting instruction (passen- aircraft) ting instruction (LQ) ting group	:	964 Y964 III	
Labe		:	Miscellaneous	
14.5 Envi	ironmental hazards			
ADR	ronmentally hazardous	:	yes	
Envi <b>RID</b>	ronmentally hazardous	:	yes	
עוא				



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Environmentally hazardous		: yes	
IMDG Marine pollutant		: yes	
<b>IATA (Passenger)</b> Environmentally hazardous		: yes	
	( <b>Cargo)</b> nmentally hazardous	: yes	

#### 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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances,	:	Conditions of restriction for the fol- lowing entries should be considered:
mixtures and articles (Annex XVII)		Number on list 3
		Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation	:	Not applicable

(Annex XIV) Regulation (EC) on substances that deplete the ozone : Not applicable layer Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast) Regulation (EU) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

		Quantity 1	Quantity 2	
E1	ENVIRONMENTAL	100 t	200 t	
	HAZARDS			



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#### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

The components of this	product are reported in	n the following inventories:

AICS		not determined
DSL	:	not determined
IECSC	:	not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### **SECTION 16: Other information**

Other 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	:	May cause an allergic skin reaction.
H334	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
H360D	:	May damage the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
Full text of other abbreviation	าร	
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Repr.	:	Reproductive toxicity
Resp. Sens.	:	Respiratory sensitisation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure

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 La-



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boratory 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; 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

Aquatic Chronic 3

Sources of key data used to compile the Safety Data Sheet		data from raw material SDSs, OECD sults and European Chemicals Agen- u/
Classification of the mixtur	е:	Classification procedure:
Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method
Repr. 1A	H360D	Calculation method
Aquatic Acute 1	H400	Calculation method

H412

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.

Calculation method

NO / EN