

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

1.1	Product identifier		
	Trade name	:	Gentamicin / Cloxacillin Formulation
1.2	Relevant identified uses of the	ne s	ubstance 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	safe	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)

Skin sensitisation, Category 1 Reproductive toxicity, Category 1A Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Cateqory 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)

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



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Haz	ard pictograms		
Sigr	al word	: Danger	•
Haz	ard statements	: H317 H334	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breath- ing difficulties if inhaled.
		H360D H410	May damage the unborn child. Very toxic to aquatic life with long lasting effects.
Pred	cautionary statements	Preven	tion:
		P201 P273 P280	Obtain special instructions before use. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection.
		Respor	
		P304 +	P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
		P342 +	
		P391	Collect spillage.

## 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

CAS-No. EC-No.	Classification	Concentration (% w/w)
Index-No.		
Registration number		



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cloxa	cillin	61-72-3 200-514-7	Resp. Sens. 1; H334 Skin Sens. 1; H317	2.2
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 plent of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.	У
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 effects, both acute and delayed

Risks :

May cause an allergic skin reaction.



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	May cause allerg ties if inhaled. May damage the	y or asthma symptoms or breathing difficul- unborn child.
	other respiratory	ure may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, reac- unction syndrome).
on of any immediate	medical attention and	d special treatment needed
ent	: Treat symptomati	cally and supportively.
	28.09.2024	28.09.2024 1936780-00019 May cause allergy ties if inhaled. May damage the Excessive expose other respiratory tive airways dyste

## **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	e substance or mixture
	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
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).



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## 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. Local authorities should be advised if significant spillages cannot be contained.
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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 Local/Total ventilation		See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. 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 environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working



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		v V T e a ir	vork clothing sho Vash contaminat 'he effective ope ngineering contr ppropriate degov	g do not eat, drink or smoke. Contaminated uld not be allowed out of the workplace. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, wning and decontamination procedures, monitoring, medical surveillance and the tive controls.			
7.2 Co	onditions for safe storage,	inclue	ncluding any incompatibilities				
	equirements for storage reas and containers	ti		abelled containers. Store locked up. Keep ore in accordance with the particular national			
A	Advice on common storage		<ul> <li>Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases</li> </ul>				
7.3 Sp	ecific end use(s)						
S	pecific use(s)	: N	lo 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
1,2,3-Propanetriyl tris(12- hydroxyoctade- canoate)	139-44-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL
cloxacillin	61-72-3 TWA		100 µg/m3 (OEB 2)	Internal
	Further inform	nation: 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.



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Pers	onal protective equipr	nent			
Eye/f	ace protection	If the work en mists or aero Wear a faces	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols		
Hand protection Material		: Chemical-res	sistant gloves		
	and body protection iratory protection	: If adequate I sure assessr ommended g Equipment s	n or laboratory coat. ocal exhaust ventilation is not available or expo- nent demonstrates exposures outside the rec- guidelines, use respiratory protection. hould conform to I.S. EN 14387		
Filter type		: Combined pa	articulates 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

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		cosity, kinematic	:	No data available	e
		lity(ies) ter solubility	:	No data available	e
		on coefficient: n- I/water	:	Not applicable	
	Vapou	r pressure	:	No data available	e
	Relativ	ve density	:	No data available	9
	Densit	у	:	No data available	9
	Relativ	ve vapour density	:	No data available	9
		e characteristics ticle size	:	Not applicable	
9.2		nformation			
	Explos	sives	:	Not explosive	
	Oxidiz	ing properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapo	ration rate	:	No data available	9

## **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

: 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.



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## **SECTION 11: Toxicological information**

## 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Eye contact

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Indestion

#### Acute toxicity

Not classified based on available information.

Not classified based on available						
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					
	LD50 (Rat): 4,200 mg/kg Application Route: Subcutaneous					
Gentamicin:						

Acute oral toxicity :	LD50 (Rat): 8,000 - 10,000 mg/kg
	LD50 (Mouse): 10,000 mg/kg
Acute inhalation toxicity :	LC50 (Rat): > 0.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist Remarks: No mortality observed at this dose.
Acute toxicity (other routes of : administration)	LD50 (Rat): 67 - 96 mg/kg Application Route: Intravenous
	LD50 (Rat): 371 - 384 mg/kg Application Route: Intramuscular
	LDLo (Monkey): 30 mg/kg Application Route: Intravenous

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		corrosion/irritation	able	information.			
	<u>Comp</u>	onents:					
	cloxad	cillin:					
	Rema	rks	:	Not classified due	to lack of data.		
	Genta	micin:					
	Specie Result		:	Rabbit Mild skin irritation			
	Seriou	ıs eye damage/eye irr	itati	on			
	Not cla	assified based on availa	able	information.			
	<u>Comp</u>	onents:					
	cloxacillin:						
	Remai	rks	:	Not classified due	to lack of data.		
	Genta	micin:					
	Specie Result		:	Rabbit Mild eye irritation			
	Respi	ratory or skin sensitis	satio	'n			
Skin sensitisation May cause an allergic skin reaction.							
	-	ratory sensitisation ause allergy or asthma	svm	ptoms or breathing	difficulties if inhaled.		
	-	onents:	<i>cj</i>				
	cloxad	cillin:					
		ure routes	:	Dermal			
	Asses: Result		:	Probability or evic positive	ence of skin sensitisation in humans		
	Asses	sment	:	Probability of resp animal testing	iratory sensitisation in humans based on		
	Result		:	positive			
	Genta	micin:					
	Rema	rks	:	No data available			
	Germ	cell mutagenicity					

## Germ cell mutagenicity

Not classified based on available information.



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<u>Comp</u>	oonents:		
cloxa	cillin:		
Geno	toxicity in vitro	Result: ne Remarks	e: Bacterial reverse mutation assay (AMES) egative Information given is based on data obtained from bstances.
Geno	toxicity in vivo	Species: Result: ne Remarks	
Genta	amicin:		
Geno	toxicity in vitro	: Test Type Result: ne	e: In vitro mammalian cell gene mutation test egative
		Test Type Result: ee	e: Chromosome aberration test in vitro quivocal
Geno	toxicity in vivo	cytogene Species:	Mouse on Route: Intravenous injection
	<b>nogenicity</b> assified based on ava	ilable informatio	
	onents:		1.
<b>cloxa</b> Rema		: Not class	ified due to lack of data.
Genta	amicin:		
Carcir ment	nogenicity - Assess-	: No data a	available
•	oductive toxicity lamage the unborn ch	ild.	
<u>Comp</u>	oonents:		
<b>cloxa</b> Effect	<b>cillin:</b> s on fertility	Species: Application Fertility: N	e: Multi-generation study Rat on Route: Oral IOAEL: 500 mg/kg body weight o effects on fertility, No effects on reproduction pa-



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	Effects on foetal develop- ment		:	Result: No malfor	e: Oral oxicity: NOAEL: 100 mg/kg body weight mations were observed.		
				Test Type: Development Species: Rabbit Application Route: Intramuscular Developmental Toxicity: NOAEL: 250 mg/kg body weight Result: No effects on foetal development			
	Gentar	nicin:					
	Effects	on fertility	:	Species: Rat Fertility: NOAEL:	eneration reproduction toxicity study 20 mg/kg body weight cant adverse effects were reported		
	Effects on foetal develop- ment		:	Species: Rabbit	vo-foetal development oxicity: NOAEL: 3.6 mg/kg body weight o-foetal toxicity		
				Species: Rat Application Route	oxicity: LOAEL: 75 mg/kg body weight		
				Species: Mouse Application Route Developmental To	vo-foetal development :: Intraperitoneal oxicity: LOAEL: 10 mg/kg body weight tality, No malformations were observed.		
				Species: Rat Application Route Developmental To	vo-foetal development :: Intraperitoneal oxicity: LOAEL: 50 mg/kg body weight tality, No malformations were observed.		
	Reproc sessme	luctive toxicity - As- ent	:	Positive evidence human epidemiol	of adverse effects on development from ogical studies.		

## STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

Not classified based on available information.

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	<u>Comp</u>	onents:			
		<b>micin:</b> Organs sment	:	Kidney, inner ear Causes damage t exposure.	o organs through prolonged or repeated
	Repea	ited dose toxicity			
	<u>Comp</u>	onents:			
		es L ation Route ure time	:	Rat 7,000 mg/kg Intravenous 4 Weeks Hypoglycemia	
	Specie LOAEI Applica Expos	L ation Route ure time : Organs	:	Dog 3 mg/kg Intramuscular 12 Months Kidney Vomiting, Salivatio	on
	Expos		: : : :	Monkey 50 mg/kg Subcutaneous 3 Weeks Kidney, inner ear	
	Expos		:	Monkey 6 mg/kg Intramuscular 3 Weeks Blood, Kidney, inr	ner ear, Liver
	Expos	L	:	Rat 5 mg/kg 10 mg/kg Intramuscular 52 Weeks Kidney, Blood	
	Expos	L	:	Rat 12.5 mg/kg 50 mg/kg Intramuscular 13 Weeks Kidney	



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### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment

: 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.

### Experience with human exposure

### **Components:**

cloxacillin:	
Inhalation	: Remarks: May cause sensitisation of susceptible persons.
Skin contact	: Symptoms: Dermatitis
	Remarks: May irritate skin.
Eye contact	: Remarks: May irritate eyes.
Ingestion	: Symptoms: May cause, Gastrointestinal disturbance, Rash
	Remarks: May cause sensitisation of susceptible persons.
Gentamicin:	
Ingestion	: Target Organs: Kidney
-	Target Organs: inner ear
	Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal
	deafness

## **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



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				Exposure time: 7 Method: OECD T	2 h Test Guideline 201
				Exposure time: 7	ι flos-aquae (cyanobacterium)): 4.7 μg/l 2 h ēst Guideline 201
				Exposure time: 7	a flos-aquae (cyanobacterium)): 1.6 µg/l 2 h <sup>-</sup> est Guideline 201
	M-Fac icity)	tor (Acute aquatic tox-	:	100	
	Toxicit	y to microorganisms	:	EC50 : 288.7 mg Exposure time: 3 Test Type: Respi Method: OECD T	h
	M-Fac toxicity	tor (Chronic aquatic ′)	:	1	
12.2	2 Persis	stence and degradabi	lity		
	<u>Comp</u>	onents:			
	<b>Genta</b> Biodeg	<b>micin:</b> gradability	:	Result: rapidly de Biodegradation: Exposure time: 2 Method: OECD T	100 %
12.3	3 Bioac	cumulative potential			
	<u>Comp</u>	onents:			
		<b>:illin:</b> on coefficient: n- I/water	:	log Pow: 2.44	
		<b>micin:</b> on coefficient: n- I/water	:	log Pow: < -2	
12.4		<b>ty in soil</b> a available			
12.5	5 Resul	ts of PBT and vPvB a	sse	ssment	
	<u>Produ</u> Assess		:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of



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### 12.6 Endocrine disrupting properties

#### Product:

Assessment

: 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.

### 12.7 Other adverse effects

No data available

## **SECTION 13: Disposal considerations**

13.1 Waste treatment methods	
Product	<ul> <li>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.</li> </ul>
Contaminated packaging	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

## **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, : 16/21

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				N.O.S. (Gentamicin)	
IA	ΑΤΑ		:	Environmentally I (Gentamicin)	nazardous substance, liquid, n.o.s.
14.3 T	ransp	oort hazard class(es)			
				Class	Subsidiary risks
Α	DN		:	9	
Α	DR		:	9	
R	RID		:	9	
IN	MDG		:	9	
IA	ΑΤΑ		:	9	
14.4 P	Packin	g group			
P C H	Classifi	g group cation Code Identification Number	:	III M6 90 9	
P C H La	lassifi lazard abels	g group cation Code Identification Number restriction code	:	III M6 90 9 (-)	
P C H	Classifi	g group cation Code Identification Number	:	III M6 90 9	
P La	<b>MDG</b> Packing abels EmS C	g group ode	:	III 9 F-A, S-F	
P		Cargo) g instruction (cargo	:	964	
P P	Packing	) g instruction (LQ) g group	:	Y964 III Miscellaneous	
P ge P	Packing er airc Packing	Passenger) g instruction (passen- craft) g instruction (LQ) g group	:	964 Y964 III Miscellaneous	

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## 14.5 Environmental hazards

Α	D	Ν	

Environmentally hazardous	:	yes
ADR Environmentally hazardous	:	yes
<b>RID</b> Environmentally hazardous	:	yes
IMDG Marine pollutant	:	yes
IATA (Passenger) Environmentally hazardous	:	yes
IATA (Cargo) Environmentally 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, mixtures and articles (Annex XVII)	:	Conditions of restriction for the fol- lowing entries should be considered: 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
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia-	:	Not applicable



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ment and the Council concerning the export and import of dangerous chemicals REACH - List of substances subject to authorisation : Not applicable (Annex XIV) Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of					
major-	accident hazards invol	ving dangerous substa	nces.		
E1		ENVIRONMENT HAZARDS		Quantity 1 100 t	Quantity 2 200 t

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

#### The components of this product are reported in 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 abbreviatio	ons	
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
IE OEL	:	Ireland. List of Chemical Agents and Carcinogens with Occu- pational Exposure Limit Values - Code of Practice, Schedule 1



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## and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

## Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/	
Classification of the mixtur	e:	Classification procedure:	
Resp. Sens. 1	H33	Calculation method	

Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method
Repr. 1A	H360D	Calculation method
Aquatic Acute 1	H400	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



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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.

IE / EN