

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.4	28.09.2024	9372777-00009	Date of first issue: 27.08.2021

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

1.1	Product identifier Trade name	:	Gentamicin (10%) Injection Formulation
1.2	Relevant identified uses of th	e 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	saf	ety data sheet
	Company	:	MSD Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom
	Telephone	:	+1-908-740-4000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

### **1.4 Emergency telephone number**

+1-908-423-6000

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

#### 2.1 Classification of the substance or mixture

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

Reproductive toxicity, Category 1A Specific target organ toxicity - repeated exposure, Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 2 H360D: May damage the unborn child. H372: Causes damage to organs through prolonged or repeated exposure. H400: Very toxic to aquatic life.

H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

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

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



## **Gentamicin (10%) Injection Formulation**

Version 3.4	Revision Date: 28.09.2024	-	SDS Number: 0372777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
Haza	ard pictograms	:		¥_2
Sign	al word	:	Danger	•
Haza	ard statements	:	H372 Ca	ay damage the unborn child. auses damage to organs through prolonged or peated exposure.
				ery toxic to aquatic life with long lasting effects.
Prec	autionary statements	:	Prevention:	
			P264         Wi           P273         Av           P280         Wi	otain special instructions before use. ash skin thoroughly after handling. /oid release to the environment. ear protective gloves/ protective clothing/ eye otection/ face protection.
			Response:	IF averaged as accordingly Oct modified advice/
				IF exposed or concerned: Get medical advice/ tention.
			P391 Co	bllect spillage.

Hazardous components which must be listed on the label: 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.

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

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Gentamicin	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	10

# UK REACH Regulations SI 2019/758

# **Gentamicin (10%) Injection Formulation**

Version 3.4	Revision Date: 28.09.2024	SDS Number: 9372777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021	
			M-Factor (Chronic aquatic toxicity): 1	

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. 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 an	nd e	ffects, both acute and delayed
	Risks	:	May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
4.3	Indication of any immediate r	nec	lical attention and special treatment needed
	Treatment	:	Treat symptomatically and supportively.

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

5.1 Extinguishing media				
Suitable extinguishing media	:			

: Water spray Alcohol-resistant foam Carbon dioxide (CO2)



## **Gentamicin (10%) Injection Formulation**

Version 3.4	Revision Date: 28.09.2024		DS Number: 72777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
			Dry chemical	
Unsuitable extinguishing media		:	None known.	
5.2 Special	hazards arising from	the	e substance or mi	xture
Specifi fighting		:	Exposure to com	pustion products may be a hazard to health.
Hazardous combustion prod- ucts		:	Carbon oxides	
5.3 Advice	for firefighters			
	l protective equipment fighters	:		e, wear self-contained breathing apparatus. tective equipment.
Specifi ods	c extinguishing meth-	:	cumstances and Use water spray	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

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

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

Personal precautions	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
----------------------	---

### 6.2 Environmental precautions

Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water.
		If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).

### 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-	



### **Gentamicin (10%) Injection Formulation**

Version 3.4	Revision Date: 28.09.2024	SDS Number: 9372777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
		Sections 13 ar	gulations are applicable. Ind 15 of this SDS provide information regarding r national requirements.
	ence to other section ons: 7, 8, 11, 12 and 13	-	
SECTION	N 7: Handling and s	torage	
7.1 Preca	utions for safe handli	ng	
Tech	nical measures		ng measures under EXPOSURE ERSONAL PROTECTION section.
Local	/Total ventilation		ntilation is unavailable, use with local exhaust
Advic	e on safe handling	Do not breathe Do not swallow Avoid contact Wash skin tho Handle in acco practice, base sessment Keep containe Do not eat, dri	
Hygie	ene measures	flushing syster place. When u nated clothing The effective c engineering cc appropriate de industrial hygie	chemical is likely during typical use, provide eye ns and safety showers close to the working sing do not eat, drink or smoke. Wash contami- before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.
7.2 Condi	tions for safe storage	e, including any inco	ompatibilities
Requ	irements for storage and containers	: Keep in prope	rly labelled containers. Store locked up. Keep Store in accordance with the particular national

Advice on common storage : Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases

### 7.3 Specific end use(s)

Specific use(s)

: No data available



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.4	28.09.2024	9372777-00009	Date of first issue: 27.08.2021

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

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
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

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection		
Material	:	Chemical-resistant gloves
Skin and body protection Respiratory protection	:	Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	:	Particulates type (P)

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

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

Appearance Colour Odour Odour Threshold	:	liquid clear odourless No data available
рН	:	3.0 - 5.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	> 100 °C
range Flash point	:	No data available

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



### **Gentamicin (10%) Injection Formulation**

Ver 3.4	sion	Revision Date: 28.09.2024		S Number: 72777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
	Evapor	ation rate	:	1	
	Flamm	ability (solid, gas)	:	Not applicable	
		explosion limit / Upper ability limit	:	No data available	9
		explosion limit / Lower ability limit	:	No data available	9
	Vapour	· pressure	:	No data available	9
	Relativ	e vapour density	:	No data available	9
	Relativ	e density	:	No data available	9
	Density		:	No data available	9
	Partitio octanol	er solubility n coefficient: n-	:	soluble No data available No data available	
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Explosi	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
9.2		n <b>formation</b> ability (liquids)	:	No data available	9
	Molecu	ılar weight	:	No data available	9
	Particle	e size	:	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



# Gentamicin (10%) Injection Formulation

Version 3.4	Revision Date: 28.09.2024		9S Number: 72777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021			
Hazardous reactions		:	: Can react with strong oxidizing agents.				
	litions to avoid tions to avoid	:	None known.				
	npatible materials ials to avoid	:	Oxidizing agents				
No ha	rdous decomposition p zardous decomposition	pro	ducts are known.				
1.1 Infori	nation on toxicologica	l efi	iects				
Inform expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact				
	e toxicity assified based on availa	ble	information.				
<u>Comp</u>	oonents:						
	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 histration)	:	LD50 (Rat): 67 - 9 Application Route				
			LD50 (Rat): 371 - Application Route				
			LDLo (Monkey): 3 Application Route				
Not cl	corrosion/irritation assified based on availa	ble	information.				
<u>Comp</u>	oonents:						
Genta	amicin:						

Species : Rabbit

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



# Gentamicin (10%) Injection Formulation

ersion 1	Revision Date: 28.09.2024	SDS Numb 9372777-0		Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
Resul	t	: Mild sk	in irritation	
Not cl	us eye damage/eye i assified based on ava conents:		ion.	
	amicin: es	: Rabbit : Mild ey	e irritation	
Resp	iratory or skin sensi	isation		
	sensitisation assified based on ava	lable informat	ion.	
	iratory sensitisation assified based on ava	lable informat	ion.	
<u>Comp</u>	oonents:			
<b>Genta</b> Rema	a <b>micin:</b> urks	: No data	a available	
	cell mutagenicity assified based on ava	lable informat	ion.	
<u>Comp</u>	oonents:			
	amicin: toxicity in vitro		/pe: In vitro negative	o mammalian cell gene mutation test
			/pe: Chron equivocal	nosome aberration test in vitro
Geno	toxicity in vivo	cytogei Specie Applica	netic assay s: Mouse	nalian erythrocyte micronucleus test (in vivo /) e: Intravenous injection
	<b>nogenicity</b> assified based on ava	lable informat	ion.	
Com	oonents:			
	amicin: nogenicity - Assess-	: No data	a available	

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



### **Gentamicin (10%) Injection Formulation**

rsion	Revision Date: 28.09.2024		Number: 2777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
May d	oductive toxicity amage the unborn chile ponents:	d.		
Genta	micin:			
Effects	s on fertility	s I	Species: Rat Fertility: NOAEL:	eneration reproduction toxicity study 20 mg/kg body weight cant adverse effects were reported
Effects ment	s on foetal develop-	: [	Species: Rabbit	/o-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 T	vo-foetal development e: Intraperitoneal oxicity: LOAEL: 10 mg/kg body weight rtality, No malformations were observed.
		: / [	Species: Rat Application Route Developmental T	vo-foetal development e: Intraperitoneal oxicity: LOAEL: 50 mg/kg body weight rtality, No malformations were observed.
Repro sessm	ductive toxicity - As- nent		Positive evidence numan epidemiol	e of adverse effects on development from ogical studies.

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

#### **Components:**

### Gentamicin:

Target Organs	: Kidney, inner ear
Assessment	: Causes damage to organs through prolonged or repeated
	exposure.

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



# **Gentamicin (10%) Injection Formulation**

ersion .4	Revision Date: 28.09.2024	SDS Number: 9372777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
Repe	ated dose toxicity		
Com	ponents:		
Genta	amicin:		
Expo	EL cation Route sure time et Organs otoms	: Dog : 3 mg/kg : Intramuscular : 12 Months : Kidney : Vomiting, Sali : Monkey	vation
LOAE Applic Expos		: 50 mg/kg : Subcutaneous : 3 Weeks : Kidney, inner	
Expo		: Monkey : 6 mg/kg : Intramuscular : 3 Weeks : Blood, Kidney	, inner ear, Liver
Expo	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 c	ration toxicity lassified based on ava rience with human e		
-	ponents:	vhoanie	
	amicin:		
Inges		: Target Organs Target Organs Symptoms: Di deafness	



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.4	28.09.2024	9372777-00009	Date of first issue: 27.08.2021

### **SECTION 12: Ecological information**

### 12.1 Toxicity

	Components:		
	<b>Gentamicin:</b> 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 Exposure time: 72 h Method: OECD Test Guideline 201
	M-Factor (Acute aquatic tox- icity)	:	100
	Toxicity to microorganisms	:	EC50 : 288.7 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
	M-Factor (Chronic aquatic toxicity)	:	1
12.2	Persistence and degradabil	ity	
	Components:		
	Gentamicin: Biodegradability	:	Result: rapidly degradable Biodegradation: 100 % Exposure time: 28 d Method: OECD Test Guideline 314

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



### **Gentamicin (10%) Injection Formulation**

Versio 3.4	n Revision Date: 28.09.2024	-	DS Number: 372777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021	
12.3 B	ioaccumulative potential				
<u>C</u>	omponents:				
Pa	entamicin: artition coefficient: n- ctanol/water	:	log Pow: < -2		
	<b>obility in soil</b> o data available				
12.5 R	esults of PBT and vPvB a	sse	ssment		
	roduct: ssessment	:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of	
12.6 Other adverse effects					
	r <u>oduct:</u> ndocrine disrupting poten- al	:	ered to have end	nixture does not contain components consid- ocrine disrupting properties for environment REACH Article 57(f).	

### **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

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
ΙΑΤΑ	:	UN 3082

14.2 UN proper shipping name



Version 3.4	Revision Date: 28.09.2024	SDS Number: 9372777-0000	Date of last issue: 06.04.2024 9 Date of first issue: 27.08.2021
ADN		: ENVIRON N.O.S. (Gentamic	MENTALLY HAZARDOUS SUBSTANCE, LIQUID,
ADR		: ENVIRON N.O.S. (Gentamic	MENTALLY HAZARDOUS SUBSTANCE, LIQUID,
RID		: ENVIRON N.O.S. (Gentamic	MENTALLY HAZARDOUS SUBSTANCE, LIQUID,
IMDG	3	: ENVIRON N.O.S. (Gentamic	MENTALLY HAZARDOUS SUBSTANCE, LIQUID,
ΙΑΤΑ		: Environme (Gentamic	ntally hazardous substance, liquid, n.o.s. n)
14.3 Tran	sport hazard class(es)		
		Class	Subsidiary risks
ADN		: 9	
ADR		: 9	
RID		: 9	
IMDO	3	: 9	
ΙΑΤΑ		: 9	
14.4 Pack	ting group		
Class	ing group sification Code rd Identification Number Is	: III : M6 : 90 : 9	
ADR Packi Class Haza Labe	ing group sification Code rd Identification Number	: III : M6 : 90 : 9 : (-)	
Class	ing group sification Code rd Identification Number Is	: III : M6 : 90 : 9	
Label EmS	ing group	: III : 9 : F-A, S-F	

IATA (Cargo)

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



### Gentamicin (10%) Injection Formulation

Ver 3.4	sion	Revision Date: 28.09.2024	-	DS Number: 372777-00009	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
	aircraft Packin	g instruction (LQ) g group	:	964 Y964 III Miscellaneous	
	Packin ger aire Packin	g instruction (LQ) g group	:	964 Y964 III Miscellaneous	
14.5 Environmental hazards					
	<b>ADN</b> Enviror	nmentally hazardous	:	yes	
	<b>ADR</b> Enviro	nmentally hazardous	:	yes	
	<b>RID</b> Enviro	nmentally hazardous	:	yes	
	<b>IMDG</b> Marine	pollutant	:	yes	
		Passenger) nmentally hazardous	:	yes	
		<b>Cargo)</b> nmentally hazardous	:	yes	
14.0	14.6 Special precautions for user				
	The transport classification(s) provided herein are for informational purposes only, and solely				

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Remarks

: Not applicable for product as supplied.

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

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)

: Conditions of restriction for the following 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

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



### **Gentamicin (10%) Injection Formulation**

Version 3.4	Revision Date: 28.09.2024	SDS Number: 9372777-00009		f last issue: 06.04.2 f first issue: 27.08.2	
				tions in correspondered to the termine whether	e refer to the condi- nding Regulation to er an entry is appli- ng on the market or
	REACH Candidate list on Acern (SVHC) for Authoris	, ,	י ר	Not applicable	
Th	e Persistent Órganic Pollu gulation (EU) 2019/1021	utants Regulations (retai		Not applicable	
	gulation (EC) on substan	ces that deplete the ozo	ne :	Not applicable	
	REACH List of substanc	es subject to authorisati	on :	Not applicable	
	B Export and import of haz ormed Consent (PIC) Rec		r:	Not applicable	
Co	ntrol of Major Accident Ha	azards Regulations 2015	5 (COMA	AH)	
E1	-	ENVIRONMENTA HAZARDS	۸L	Quantity 1 100 t	Quantity 2 200 t

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

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

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

AICS	:	not determined
DSL	:	not determined
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 are highlighted in the body of this document by two lines.	
Full text of H-Statements		

H360D H372	<ul><li>May damage the unborn child.</li><li>Causes damage to organs through prolonged or repeated</li></ul>
11372	exposure if swallowed.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.



### Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.4	28.09.2024	9372777-00009	Date of first issue: 27.08.2021

#### Full text of other abbreviations

Aquatic Acute :	Short-term (acute) aquatic hazard
Aquatic Chronic :	Long-term (chronic) aquatic hazard
Repr. :	Reproductive toxicity
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 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to : 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 mixture:**

Repr. 1A	H360D
STOT RE 1	H372
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

#### **Classification procedure:**

Calculation method Calculation method Calculation method Calculation method



### **Gentamicin (10%) Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.4	28.09.2024	9372777-00009	Date of first issue: 27.08.2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN