according to GB/T 16483 and GB/T 17519



Gentamicin (10%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/04/06
4.0	2024/09/28	804040-00019	Date of first issue: 2016/07/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Gentamicin (10%) Injection Formulation
Manufacturer or supplier's de	ətai	
Company	:	MSD
Address	:	No. 485 Jing Tai Road Pu Tuo District - Shanghai - China 200331
Telephone	:	+1-908-740-4000
Emergency telephone number	:	86-571-87268110
E-mail address	:	EHSDATASTEWARD@msd.com
Recommended use of the ch	em	ical and restrictions on use
Recommended use Restrictions on use	:	Veterinary product Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance Colour Odour	:	liquid clear odourless
, ,		uses damage to organs through prolonged or repeated expo- kic to aquatic life with long lasting effects.
GHS Classification		
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

GHS label elements

according to GB/T 16483 and GB/T 17519



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ersion)	Revision Date: 2024/09/28	SDS Number: 804040-00019	Date of last issue: 2024/04/06 Date of first issue: 2016/07/15
Hazaı	rd pictograms		
Signa	l word	: Danger	V
Hazaı	rd statements	H372 Cause exposure. H400 Very t	damage the unborn child. es damage to organs through prolonged or repeat oxic to aquatic life. to aquatic life with long lasting effects.
Preca	utionary statements	P202 Do no and underst P260 Do no P264 Wash P270 Do no P273 Avoid	n special instructions before use. t handle until all safety precautions have been rea ood. t breathe mist or vapours. skin thoroughly after handling. t eat, drink or smoke when using this product. release to the environment. protective gloves/ protective clothing/ eye protec-
		Response: P308 + P31 attention. P391 Collect	3 IF exposed or concerned: Get medical advice/
		Storage: P405 Store	locked up.
		Disposal: P501 Dispos disposal pla	se of contents/ container to an approved waste nt.
-	ical and chemical had lassified based on avai		
Healt	h hazards		to organs through prolonged or repeated expo-

Environmental hazards

Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

according to GB/T 16483 and GB/T 17519



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Components

Chemical name	CAS-No.	Concentration (% w/w)
Gentamicin	1403-66-3	10

4. 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.
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.
Most important symptoms	:	May damage the unborn child.
and effects, both acute and delayed		Causes damage to organs through prolonged or repeated exposure.
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).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides
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.



according to GB/T 16483 and GB/T 17519

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	Specia	l protective equipment		so. Evacuate area.	ged containers from fire area if it is safe to do
	for firef		•	Use personal prof	
6. A	CCIDE	NTAL RELEASE MEAS	SUF	RES	
	tive eq	al precautions, protec- uipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
	Enviror	nmental precautions	:	Prevent spreading barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages
		ds and materials for iment and cleaning up	:	For large spills, pu ment to keep mat be pumped, store Clean up remainin bent. Local or national u posal of this mate employed in the c mine which regula Sections 13 and 1	a absorbent material. Tovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. In materials from spill with suitable absor- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements.
7. H		NG AND STORAGE			
	Handli	na			
		cal measures	:		measures under EXPOSURE
	Local/T	otal ventilation	:		SONAL PROTECTION section. tion is unavailable, use with local exhaust

Advice on safe handling	ventilation. Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow.
	Avoid contact with eyes.
	Wash skin thoroughly after handling.
	Handle in accordance with good industrial hygiene and safety
	practice, based on the results of the workplace exposure as-

according to GB/T 16483 and GB/T 17519



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Avoidance of contact			sessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize relea environment.	
_		•	Oxidizing agents	
Stora	ge			
	tions for safe storage	:	Store locked up. Keep tightly close Store in accordan	ce with the particular national regulations.
Materi	ials to avoid	:	Do not store with Strong oxidizing a	the following product types: agents
Packa	iging material	:	Unsuitable materi	al: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis			
		exposure)	concentration				
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB 2)	Internal			
	Further info	mation: OTO					
Engineering measures	technologie less quick of All enginee design and protect pro	es to control airbo connections). ring controls shou operated in acco ducts, workers, ai	controls and manufact rne concentrations (e. uld be implemented by rdance with GMP prin nd the environment. t require special conta	g., drip- / facility ciples to			
Personal protective equipm	ent						
Respiratory protection	sure asses	sment demonstra	ntilation is not availabl tes exposures outside espiratory protection.				
Filter type Eye/face protection	: Wear safet If the work mists or ae Wear a fac	Particulates type 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					
Skin and body protection Hand protection		rm or laboratory o	oat.				
Material	: Chemical-r	esistant gloves					



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Hygie	ene measures	eye flushing sy ing place. When using do Wash contamin The effective o engineering co appropriate de industrial hygie	chemical is likely during typical use, provide vstems and safety showers close to the work- o not eat, drink or smoke. nated clothing before re-use. peration of a facility should include review of ontrols, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	clear
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	3.0 - 5.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	> 100 °C
Flash point	:	No data available
Evaporation rate	:	1
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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	soluble

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	tion coefficient: n- nol/water	:	No data available	9
00101	-ignition temperature	:	No data available)
Deco	omposition temperature	:	No data available)
Visco V	osity iscosity, kinematic	:	No data available	
Expl	osive properties	:	Not explosive	
Oxid	izing properties	:	The substance of	r mixture is not classified as oxidizing.
Mole	cular weight	:	No data available	9
	cle characteristics cle size	:	No data available)

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition	:	No hazardous decomposition products are known.
products		

11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation
	Skin contact
	Ingestion
	Eye contact

Acute toxicity

Not classified based on available information.

Components:

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

according to GB/T 16483 and GB/T 17519



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	e toxicity (other routes of inistration)	: LD50 (Ra Applicatio LD50 (Ra Applicatio LDLo (Mc	n Route: Intravenous t): 371 - 384 mg/kg n Route: Intramuscular nkey): 30 mg/kg
	corrosion/irritation		n Route: Intravenous
Com	ponents:		
Gen Spec Rest		: Rabbit : Mild skin i	rritation
Not	ous eye damage/eye irri classified based on availa aponents:		۱.
Gen Spec Rest		: Rabbit : Mild eye i	rritation
Skin Not d Resj	piratory or skin sensitis sensitisation classified based on availa piratory sensitisation classified based on availa	ble informatior	
	nponents: tamicin: narks	: No data a	vailable
Not	n cell mutagenicity classified based on availa pponents:	ble informatior	۱.
Gen Gen	tamicin: otoxicity in vitro	: Test Type Result: ne	e: In vitro mammalian cell gene mutation test egative

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Geno	toxicity in vivo	Result: equiv : Test Type: N cytogenetic a Species: Mo	lammalian erythrocyte micronucleus test (in vivo assay) use Route: Intravenous injection
	i nogenicity lassified based on ava	lable information.	
Com	ponents:		
Gent	amicin:		
Carci ment	nogenicity - Assess-	: No data avai	lable
-	oductive toxicity damage the unborn chi	ld.	
Com	ponents:		
Gent	amicin:		
Effec	ts on fertility	Species: Rat Fertility: NOA	wo-generation reproduction toxicity study AEL: 20 mg/kg body weight gnificant adverse effects were reported
Effec ment	ts on foetal develop-	Species: Rat Developmen	mbryo-foetal development obit tal Toxicity: NOAEL: 3.6 mg/kg body weight mbryo-foetal toxicity
		Species: Rat Application F Developmen	mbryo-foetal development Route: Intraperitoneal tal Toxicity: LOAEL: 75 mg/kg body weight ryo-foetal toxicity
		Species: Mo Application F Developmen	mbryo-foetal development use Route: Intraperitoneal tal Toxicity: LOAEL: 10 mg/kg body weight I mortality, No malformations were observed.
		Species: Rat Application F Developmen	mbryo-foetal development Route: Intraperitoneal tal Toxicity: LOAEL: 50 mg/kg body weight I mortality, No malformations were observed.

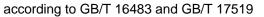
according to GB/T 16483 and GB/T 17519



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Repro	oductive toxicity - As-	· Positive evi	dence of adverse effects on development from
sessn			lemiological studies.
	Γ - single exposure lassified based on avai	able information.	
	- repeated exposure		
	es damage to organs th	rough prolonged	or repeated exposure.
Comp	ponents:		
	amicin:		
	et Organs ssment	: Kidney, inn	er ear nage to organs through prolonged or repeated
73300	Sameric	exposure.	hage to organs through protonged or repeated
Repe	ated dose toxicity		
-	ponents:		
	amicin:		
Speci		: Dog	
LOAE		: 3 mg/kg	
	cation Route	: Intramuscu	ar
	sure time	: 12 Months	
Large	et Organs	: Kidney	alivetian
Symp	otoms	: Vomiting, S	anvation
Speci	ies	: Monkey	
LOAE		: 50 mg/kg	
Applic	cation Route	: Subcutaneo	DUS
	sure time et Organs	: 3 Weeks : Kidney, inn	er ear
	Ū	. Rancy, min	
Speci		: Monkey	
LOAE		: 6 mg/kg	
	cation Route sure time	: Intramuscul : 3 Weeks	ar
	et Organs		ey, inner ear, Liver
Speci	ies	: Rat	
NOAE		: 5 mg/kg	
LOAE		: 10 mg/kg	
Applic	cation Route	: Intramuscu	ar
	sure time	: 52 Weeks	
Targe	et Organs	: Kidney, Blo	od
Speci		: Rat	
NOAE		: 12.5 mg/kg	
LOAE	-	: 50 mg/kg	

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Application Route Exposure time Target Organs	:	Intramuscular 13 Weeks Kidney
Aspiration toxicity		
Not classified based on availa	ble	information.
Experience with human exp	osi	ire
Components:		
Gentamicin:		
Ingestion	:	Target Organs: Kidney Target Organs: inner ear Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness
12. ECOLOGICAL INFORMATION	N	
Ecotoxicity		
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 Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic tox- icity)	:	100

according to GB/T 16483 and GB/T 17519



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M-Fact toxicity	or (Chronic aquatic	:	1	
	y to microorganisms	:	EC50: 288.7 mg/l Exposure time: 3 Test Type: Respir Method: OECD To	h ration inhibition
Persis	tence and degradabil	ity		
Comp	onents:			
Gental Biodeg	micin: Iradability	:	Result: rapidly de Biodegradation: 7 Exposure time: 28 Method: OECD To	100 % 3 d
Bioaco	cumulative potential			
Comp	onents:			
Genta Partitio octano	n coefficient: n-	:	log Pow: < -2	
	t y in soil a available			
	adverse effects a available			
13. DISPOS	SAL CONSIDERATION	NS		
-	sal methods from residues	:	Do not dispose of Dispose of in acco	waste into sewer. ordance with local regulations.
Contar	ninated packaging	:	Empty containers dling site for recyc	should be taken to an approved waste han-
14. TRANS	PORT INFORMATION	I		
Interna	ational Regulations			
UNRTI UN nui Proper			UN 3082 ENVIRONMENTA N.O.S. (Gentamicin)	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Class		:	9	
			12 / 15	



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Labe	ing group Is onmentally hazardous	: III : 9 : yes	
IATA UN/IE	-DGR D No. er shipping name	: UN 3082	v hazardous substance, liquid, n.o.s.
Packi Label Packi aircra Packi ger a	ing group ls ing instruction (cargo	: III : Miscellaneous : 964 : 964	
IMDG UN n	G-Code umber er shipping name	: yes : UN 3082 : ENVIRONMEN N.O.S. (Gentamicin)	TALLY HAZARDOUS SUBSTANCE, LIQUID,
Label EmS	ing group	: 9 : III : 9 : F-A, S-F : yes	
Not a	pplicable for product as		POL 73/78 and the IBC Code
Natio	onal Regulations		
UN n	944/12268 umber er shipping name	N.O.S.	TALLY HAZARDOUS SUBSTANCE, LIQUID,
Labe	ing group	(Gentamicin) : 9 : III : 9 : no	
	ial precautions for use	r	
The the t	ransport classification(s) d upon the properties of	provided herein are the unpackaged mat	for informational purposes only, and solely erial as it is described within this Safety Data node of transportation, package sizes, and var-

ortation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information Law on the Prevention and Control of Occupational Diseases

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l	Regulations on Safety Mar	nage	ment of Hazardo	us Cher	nicals
	Catalogue of Hazardous Che	emic	als	:	This product is not listed in the cata- logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de- termination.
	dentification of Major Hazar 18218)	d Ins	tallations for Haza	ardous C	Chemicals (GB : Not listed
	Hazardous Chemicals for Pr SAWS	iority	Management und	ler :	Not listed
	Regulations on Labour Pro	otect	ion in Workplace	s wher	e Toxic Substances are Used
	Catalogue of Highly Toxic C		•	:	Not listed
	Regulation of Environmen and Export of Toxic Chem			ne First	Import of Chemicals and the Import
I	China Severely Restricted T and Export			ort :	Not listed
	Desculation on the Adminis	4		Chamia	
	Regulation on the Adminis Catalogue and Classification				Not listed
	Yangtze River Protection L	_aw			
-	This product does not contai	in an	y dangerous chem	nicals pr	ohibited for inland river transport.
-	The components of this pr	odu	ct are reported in	the fol	lowing inventories:
	AICS	:	not determined		-
I	DSL	:	not determined		
I	ECSC	:	not determined		
16. O	THER INFORMATION				
I	Revision Date	:	2024/09/28		
;	Further information Sources of key data used to compile the Safety Data Sheet	:		earch re	lata from raw material SDSs, OECD sults and European Chemicals Agen- J
	tems where changes have b document by two vertical line		made to the previ	ous vers	sion are highlighted in the body of this
I	Date format	:	yyyy/mm/dd		



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Full text of other abbreviations

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

Disclaimer

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

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