

Vers 6.2	ion	Revision Date: 30.09.2023		S Number: 1050-00018		sue: 04.04.2023 sue: 15.07.2016
Sect	ion 1: I	dentification				
	Produc	t name	:	Gentamicin (10%	b) Injection Forn	nulation
	Manufa	acturer or supplier's d	letai	ils		
	Compa		:	MSD		
Address		:	33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand			
	Teleph	one	:	0800 800 543		
	Emerge	ency telephone number	• :	0800 764 766 (08 CHEMCALL)	800 POISON)	0800 243 622 (0800
	E-mail	address	:	EHSDATASTEW	/ARD@msd.cor	n
	Recom	mended use of the cl	nem	ical and restriction	ons on use	
Recommended use Restrictions on use		:	Veterinary produ Not applicable	ct		
Sect	ion 2: I	Hazard identification				
	<u>сне с</u>	lassification				
		uctive toxicity	:	Category 1		
	Specific	c target organ toxicity - ed exposure (Oral)	:	Category 1 (Kidn	ey, inner ear)	
		ous to the aquatic ment - acute hazard	:	Category 1		
		ous to the aquatic ment - chronic hazard	:	Category 2		

GHS label elements

Hazard pictograms

Signal word

Hazard statements

H360D May damage the unborn child. H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed. H400 Very toxic to aquatic life.

:

:

:

Danger



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		H411 Toxic to	aquatic life with lo	ng lasting effects.
Preca	autionary statements	[:] Prevention:		
		P260 Do not l P264 Wash s P270 Do not e P273 Avoid re	elease to the enviro rotective gloves/ pr	ours. r handling. s when using this product.
		Response: P308 + P313 attention. P391 Collect		cerned: Get medical advice/
		Storage: P405 Store lo	cked up.	
		Disposal: P501 Dispose disposal plant		iner to an approved waste
Othe	r hazards which do r	ot result in classific	ation	
None	known.			
Section 3	: Composition/inform	nation on ingredients	\$	
Subs	tance / Mixture	: Mixture		
Com	ponents			
Chen	nical name		CAS-No.	Concentration (% w/w)

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

Section 4: First-aid measures

General advice	 In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. 	
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.	



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Ma ar de Pr No	swallowed ost important symptoms id effects, both acute and elayed otection of first-aiders otes to physician	Get medical atte Rinse mouth the May damage the Causes damage exposure if swa First Aid respon and use the rec when the potent Treat symptoma	oroughly with water. e unborn child. e to organs through prolonged or repeated
Sectio	n 5: Fire-fighting measure	S	
Su	uitable extinguishing media	: Water spray Alcohol-resistan Carbon dioxide Dry chemical	
	nsuitable extinguishing edia	: None known.	
Sp	becific hazards during fire-	: Exposure to cor	nbustion products may be a hazard to health.
	azardous combustion prod-	: Carbon oxides	
Sr oc	becific extinguishing meth- Is	cumstances and Use water spray Remove undam	ng measures that are appropriate to local cir- I the surrounding environment. I to cool unopened containers. aged containers from fire area if it is safe to do
fo	pecial protective equipment r firefighters azchem Code		re, wear self-contained breathing apparatus. otective equipment.
Sectio	n 6: Accidental release me	easures	
tiv	ersonal precautions, protec- e equipment and emer- ency procedures	Follow safe han	otective equipment. dling advice (see section 7) and personal pro- nt recommendations (see section 8).
Er	nvironmental precautions	Prevent further Prevent spreadi barriers). Retain and disp	the environment. eakage or spillage if safe to do so. ng over a wide area (e.g. by containment or oil ose of contaminated wash water. s should be advised if significant spillages ined.
	ethods and materials for Intainment and cleaning up	For large spills, ment to keep m be pumped, sto	ert absorbent material. provide dyking or other appropriate contain- aterial from spreading. If dyked material can re recovered material in appropriate container. hing materials from spill with suitable absor-



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		posal of this ma employed in the mine which reg Sections 13 an	al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.
Section 7	: Handling and storag	e	
Tech	nical measures		ng measures under EXPOSURE ERSONAL PROTECTION section.
Local	/Total ventilation		tilation is unavailable, use with local exhaust
	e on safe handling	Do not swallow Avoid contact w Wash skin thor Handle in acco practice, based sessment Keep container Do not eat, drir Take care to pr environment.	mist or vapours. vith eyes. oughly after handling. rdance with good industrial hygiene and safety I on the results of the workplace exposure as- tightly closed. k or smoke when using this product. event spills, waste and minimize release to the
Hygie	ene measures	flushing system place. When using do Wash contamir The effective o engineering co appropriate des	chemical is likely during typical use, provide eye as and safety showers close to the working not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the rative controls
Cond	itions for safe storage	: Keep in proper Store locked up Keep tightly clo	ly labelled containers.
Mate	rials to avoid		th the following product types:

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB	Internal



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		1	I		1	
			Further informatio	2) n: OTO		
Engii	neering measures	:	technologies to c less quick conner All engineering c design and opera protect products,	engineering controls and ontrol airborne concentra ctions). ontrols should be implem ated in accordance with G workers, and the environ tions do not require spec	itions (e.g., drip- ented by facility GMP principles to ment.	
	onal protective equipme	ent				
Fil Hand	iratory protection Iter type protection aterial	:	sure assessment	exhaust ventilation is not demonstrates exposures elines, use respiratory pro	s outside the rec-	
	protection	:	If the work enviro mists or aerosols Wear a faceshiel potential for direct aerosols.	ses with side shields or g nment or activity involves , wear the appropriate go d or other full face protec t contact to the face with	s dusty conditions, oggles. tion if there is a	
Skin	and body protection	:	Work uniform or	aboratory coat.		
tion 9	: Physical and chemica	l pr	operties			
Appe	arance	:	liquid			
Colou	ır	:	clear			
Odou	r	:	odourless			
Odou	r Threshold	:	No data availabl	е		
рН		:	3.0 - 5.5			
Meltir	ng point/freezing point	:	No data availabl	e		
Initial range	boiling point and boiling	:	> 100 °C			
Flash	point	:	No data availabl	е		
Evap	oration rate	:	1			

Flammability (solid, gas)

: Not applicable



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		explosion limit / Upper bility limit	:	No data available	9
		explosion limit / Lower bility limit	:	No data available	9
	Vapour	pressure	:	No data available	2
	Relative	e vapour density	:	No data available	2
	Relative	e density	:	No data available	9
	Density	/	:	No data available	9
	Solubili Wat	ity(ies) er solubility	:	soluble	
	Partitio octanol	n coefficient: n-	:	No data available	9
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidiziı	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	9
	Particle	e size	:	No data available	9

Section 10: Stability and reactivity

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

Section 11: Toxicological information

Exposure routes	: Inhalation
	Skin contact
	Ingestion



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			Eye contact	
	e toxicity lassified based on availa	ble	information.	
	ponents:			
	amicin:			
Acute	e oral toxicity	:	LD50 (Rat): 8,000	0 - 10,000 mg/kg
			LD50 (Mouse): 10	0,000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 0.2 Exposure time: 4 Test atmosphere: Remarks: No mo	h
	e toxicity (other routes of nistration)	:	LD50 (Rat): 67 - 9 Application Route	
			LD50 (Rat): 371 - Application Route	
			LDLo (Monkey): 3 Application Route	
Skin	corrosion/irritation			
Not c	lassified based on availa	ble	information.	
Com	ponents:			
	amicin:			
Spec Resu		:	Rabbit Mild skin irritation	ı
	ous eye damage/eye irri			
	lassified based on availa	ble	information.	
	ponents:			
Gent Speci	amicin:		Rabbit	
Resu		:	Mild eye irritation	
Resp	iratory or skin sensitis	atic	on	
	sensitisation			
Not c	lassified based on availa	ble	information.	

Respiratory sensitisation

Not classified based on available information.



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<u>Com</u>	ponents:			
Gent a Rema	amicin: arks	:	No data available	
Chro	nic toxicity			
	n cell mutagenicity lassified based on avail	able	information.	
<u>Com</u>	ponents:			
	amicin: toxicity in vitro	:	Test Type: In vitro Result: negative	o mammalian cell gene mutation test
			Test Type: Chron Result: equivocal	nosome aberration test in vitro
Geno	toxicity in vivo	:	cytogenetic assay Species: Mouse	nalian erythrocyte micronucleus test (in vivo /) : Intravenous injection
	i nogenicity lassified based on avail	able	information.	
<u>Com</u>	ponents:			
	amicin: nogenicity - Assess-	:	No data available	
-	oductive toxicity	d.		
<u>Com</u>	ponents:			
	amicin: ts on fertility	:	Species: Rat Fertility: NOAEL:	eneration reproduction toxicity study 20 mg/kg body weight cant adverse effects were reported
Effect ment	ts on foetal develop-	:	Species: Rabbit	ro-foetal development oxicity: NOAEL: 3.6 mg/kg body weight o-foetal toxicity
			Test Type: Embry Species: Rat Application Route	ro-foetal development : Intraperitoneal



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			Developmental T Result: Embryo-f	oxicity: LOAEL: 75 mg/kg body weight oetal toxicity	
			Species: Mouse Application Route Developmental T	yo-foetal development e: Intraperitoneal oxicity: LOAEL: 10 mg/kg body weight rtality, 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 observe		
•	roductive toxicity - As- ment	:	Positive evidence human epidemio	e of adverse effects on development from logical studies.	

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swal-lowed.

Components:

Gentamicin:

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

Dog
3 mg/kg
Intramuscular
12 Months
Kidney

: Vomiting, Salivation

Repeated dose toxicity

Components:

Gentamicin:

Species	: Monkey
LOAEL	: 50 mg/kg
Application Route	: Subcutaneous
Exposure time	: 3 Weeks
Target Organs	: Kidney, inner ear
Species	: Monkey
LOAEL	: 6 mg/kg



/ersion 5.2	Revision Date: 30.09.2023		0S Number: 4050-00018	Date of last issue: 04.04.2023 Date of first issue: 15.07.2016	
Expos Targe Speci NOAI LOAE Applic Expos	EL		Intramuscular 3 Weeks Blood, Kidney, inr Rat 5 mg/kg 10 mg/kg Intramuscular 52 Weeks Kidney, Blood	her ear, Liver	
NOAE LOAE Applic Expos	Species NOAEL LOAEL Application Route Exposure time Target Organs		Rat 12.5 mg/kg 50 mg/kg Intramuscular 13 Weeks Kidney		
Not c	ration toxicity lassified based on availa rience with human exp				
<u>Com</u>	ponents:				
	amicin:				
Inges	tion	:	Target Organs: Ki Target Organs: in Symptoms: Dizzin deafness		
Section 1	2: Ecological information	on			
Ecoto	oxicity				
<u>Com</u>	ponents:				
Genta	amicin:				
	ity to daphnia and other tic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te		
			LC50 (Americamy Exposure time: 96 Method: US-EPA		
Toxic plants	ity to algae/aquatic s	:	EC50 (Pseudokiro Exposure time: 72 Method: OECD Te		
			NOEC (Pseudokir µg/l	chneriella subcapitata (green algae)): 1.5	



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			Exposure time: Method: OECD	72 h Test Guideline 201
			Exposure time:	a flos-aquae (cyanobacterium)): 4.7 μg/l 72 h Test Guideline 201
			Exposure time:	na flos-aquae (cyanobacterium)): 1.6 μg/l 72 h Test Guideline 201
	ctor (Acute aquatic tox-	:	100	
icity) M-Fao	ctor (Chronic aquatic	:	1	
toxicit Toxici	y) ity to microorganisms	:		
Persi	stence and degradabil	ity		
<u>Comp</u>	ponents:			
	amicin: gradability	:	Result: rapidly o Biodegradation: Exposure time: Method: OECD	100 %
Bioad	cumulative potential			
<u>Comp</u>	oonents:			
Partiti	amicin: on coefficient: n- ol/water	:	log Pow: < -2	
	l ity in soil ata available			
	r adverse effects ata available			
tion 1	3: Disposal considerat	ion	6	
Dispo	osal methods			
-	e from residues		Do not dispose	of waste into sewer.

Dispose of in accordance with local regulations.	
Contaminated packaging : Empty containers should be taken to an approve dling site for recycling or disposal. If not otherwise specified: Dispose of as unused	



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Section 14: Transport information

International Regulations

UNRTDG		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passen- ger aircraft)	:	964
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Class		(Gentamicin)
Class	:	9
Packing group	:	
Labels	÷	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

NZS 5433 UN number Proper shipping name	:	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)
Class	:	9
Packing group	:	III
Labels	:	9
Hazchem Code	:	3Z
Marine pollutant	:	no



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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.

Section 15: Regulatory information

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

HSNO Approval Number

not allocated

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

Section 16: Other information

Revision Date	:	30.09.2023
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 Agen- cy, http://echa.europa.eu/
Date format	:	dd.mm.yyyy

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;



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n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

NZ / EN