

Version 1.6	Revision Date: 10.10.2020	-	S Number: 5023-00007	Date of last issue: 13.09.2019 Date of first issue: 25.07.2017
Sectior	1: Identification			
Pro	oduct name	:	Gentamicin (8%)	Injection Formulation
	nufacturer or supplier's d	etai		
0	mpany		Organon & Co.	
Ad	dress	:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302
Te	lephone	:	551-430-6000	
En	nergency telephone number		215-631-6999	
E-r	nail address	:	EHSSTEWARD@	⊉organon.com
	commended use of the ch commended use	nemi :	i cal and restrictic Pharmaceutical	ons on use
Sectior	2: Hazard identification			
Gŀ	IS Classification			
Re	productive toxicity	:	Category 1A	
•	ecific target organ toxicity - beated exposure (Oral)	:	Category 2 (Kidn	ey, inner ear)
Gŀ	IS label elements			
На	zard pictograms	:		
Sig	inal word	:	Danger	
На	zard statements	:	H373 May cause	age the unborn child. damage to organs (Kidney, inner ear) through eated exposure if swallowed.
Pre	ecautionary statements	:	Prevention:	
			P201 Obtain spee P202 Do not han and understood. P260 Do not brea	cial instructions before use. dle until all safety precautions have been read athe mist or vapours. al protective equipment as required.
			Response: P308 + P313 IF e attention.	exposed or concerned: Get medical advice/
			Storage:	



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			P405 Store lo	cked up.				
			Disposal:	·				
			-					
	P501 Dispose of contents/ container to an approved was disposal plant.							
Othe	r hazards which do no	ot res	sult in classifica	ation				
None	known.							
ction 3	: Composition/informa	atior	on ingredients	5				
Subst	tance / Mixture	:	Mixture					
Com	ponents							
Cherr	nical name			CAS-No.	Concentration (% w/w)			
Genta	amicin			1403-66-3	8			
Benz	yl alcohol			100-51-6	1.5			
Gene	eral advice	:	vice immediate When symptor	ely.	feel unwell, seek medical ad- l cases of doubt seek medical			
			advice.					
lf inha	aled	:	: If inhaled, remove to fresh air. Get medical attention.					
In cas	se of skin contact	 In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. 						
			Get medical at Wash clothing	tention. before reuse.				
In cas	se of eye contact	:	Flush eyes with	an shoes before h water as a prec	aution.			
lf swa	allowed	:	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention.					
Most important symptoms : May dama				noroughly with wa ne unborn child.				
and a	offacts both acute and		Nav cauco dar	nade to ordane th	prough prolonged or repeated			

and effects, both acute and delayed		May cause damage to organs through prolonged or repeated exposure if swallowed.
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.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.



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	Specific hazards fighting	s during fire-	:		a explosive mixtures with air. ustion products may be a hazard to health.
	Hazardous com ucts	bustion prod-	:	Carbon oxides	
	Specific extingu ods	ishing meth-	:	cumstances and the Use water spray to	measures that are appropriate to local cir- ne surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	Special protective for firefighters Hazchem Code	ve equipment	:	In the event of fire Use personal prot 3Z	, wear self-contained breathing apparatus. ective equipment.

Section 6: Accidental release measures

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
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.
Methods and materials for containment and 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.

Section 7: Handling and storage

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling.



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Hygiene measures		 practice, based of sessment Keep container titic Do not eat, drink Take care to prevenvironment. If exposure to chase flushing systems place. When using do no Wash contamina The effective operation 	lance with good industrial hygiene and safety on the results of the workplace exposure as- ightly closed. or smoke when using this product. vent spills, waste and minimize release to the emical is likely during typical use, provide eye and safety showers close to the working not eat, drink or smoke. ted clothing before re-use. eration of a facility should include review of rols, proper personal protective equipment,		
Conc	litions for safe storage	 appropriate degowning and decontamination procedures industrial hygiene monitoring, medical surveillance and to use of administrative controls. Keep in properly labelled containers. Store locked up. Keep tightly closed. 			
Mate	rials to avoid	Store in accorda	nce with the particular national regulations. 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 2)	Internal
Engineering measures	technologies less quick cor All engineerin design and op protect produ	to control airborr nnections). Ig controls shoul perated in accorr cts, workers, and	controls and manufac ne concentrations (e.g d be implemented by dance with GMP princ d the environment. require special contai	g., drip- facility ciples to

_	_			
Per	sonal prote	ective equipm	ent	
1 61	Sonai prou		CIIL	

Respiratory protection		If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type Hand protection	:	Combined particulates and organic vapour type
Material	:	Chemical-resistant gloves
Eye 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

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Skin a	and body protection	:	potential for direct aerosols. Work uniform or la	t contact to the face with dusts, mists, or aboratory coat.
Section 9:	Physical and chemica	l pr	operties	
Арреа	arance	:	liquid	
Colou	r	:	colourless	
Odou	r	:	No data available	9
Odou	r Threshold	:	No data available	9
рН		:	No data available	9
Meltin	g point/freezing point	:	No data available	9
Initial range	boiling point and boiling	:	No data available	9
Flash	point	:	> 93.3 °C	
Evapo	pration rate	:	No data available	9
Flamr	nability (solid, gas)	:	Not applicable	
Flamr	nability (liquids)	:	Not applicable	
	r explosion limit / Upper nability limit	:	No data available	9
	r explosion limit / Lower nability limit	:	No data available	9
Vapou	ur pressure	:	No data available	9
Relati	ve vapour density	:	No data available	9
Relati	ve density	:	No data available	9
Densi	ty	:	No data available	9
	ility(ies) ater solubility	:	No data available	9
octan	on coefficient: n- ol/water	:	No data available	
	gnition temperature	:	No data available	
	mposition temperature	:	No data available	9
Visco Vis	sity scosity, kinematic	:	No data available	9



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Explo	osive properties	÷	Not explosive			
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.		
Mole	cular weight	:	No data available	9		
Partic	cle size	:	No data available	e		
Section 1	0: Stability and reactivi	ty				
	tivity nical stability ibility of hazardous reac-	:	Stable under nor Vapours may for	a reactivity hazard. mal conditions. m explosive mixture with air. arong oxidizing agents.		
Incon	litions to avoid npatible materials rdous decomposition ucts		None known. Oxidizing agents No hazardous decomposition products are known.			
Section 1	1: Toxicological inform	atio	n			
Ехро	sure routes	:	Inhalation Skin contact Ingestion Eye contact			
	e toxicity lassified based on availa	ble i	information.			
Prod	uct:					
	e oral toxicity	:	Acute toxicity esti Method: Calculati	mate: > 2,000 mg/kg on method		
Acute	e inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method			
Com	ponents:					
	amicin: e oral toxicity	:	LD50 (Rat): 8,000) - 10,000 mg/kg		
		:	LD50 (Rat): 8,000 LD50 (Mouse): 10			
Acute		:	LD50 (Mouse): 10 LC50 (Rat): > 0.2 Exposure time: 4 Test atmosphere:	0,000 mg/kg mg/l h		



rsion	Revision Date: 10.10.2020		OS Number: 45023-00007	Date of last issue: 13.09.2019 Date of first issue: 25.07.2017
admir	nistration)		Application Route	e: Intravenous
			LD50 (Rat): 371 Application Route	
			LDLo (Monkey): Application Route	
Benz	yl alcohol:			
Acute	oral toxicity	:	LD50 (Rat): 1,62	0 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 4.1 Exposure time: 4 Test atmosphere Method: OECD T	h
-	corrosion/irritation assified based on ava	ailable	information.	
<u>Comp</u>	oonents:			
Genta	amicin:			
Speci Resul		:	Rabbit Mild skin irritatior	1
Benz	yl alcohol:			
Speci	es	:	Rabbit	
Metho Resul		:	OECD Test Guid No skin irritation	eine 404
	us eye damage/eye assified based on ava			
<u>Comp</u>	oonents:			
Genta	amicin:			
Speci Resul		:	Rabbit Mild eye irritation	
Benz	yl alcohol:			
Speci		:	Rabbit	
Resul Metho		:	OECD Test Guid	reversing within 21 days eline 405
Resp	iratory or skin sensi	tisatio	on	
-	sensitisation assified based on ava	ailable	information.	
Resp	iratory sensitisation			
Not cl	assified based on ava	allahla	information	

Not classified based on available information.



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<u>Com</u> p	oonents:			
Genta	amicin:			
Rema	rks	: No da	ata available	
Bonz	yl alcohol:			
Test 7		· Mavir	nisation Tes	+
	sure routes		contact	
Speci		: Guine		
Metho			D Test Guid	eline 406
Resul	t	: negat	ive	
Chro	nic toxicity			
	cell mutagenicity			
Not cl	assified based on av	ailable inform	ation.	
<u>Comp</u>	oonents:			
Genta	amicin:			
Geno	toxicity in vitro		Type: In vitro lt: negative	o mammalian cell gene mutation test
			Type: Chron lt: equivocal	nosome aberration test in vitro
Genot	toxicity in vivo	cytog Speci Applio	enetic assa es: Mouse	nalian erythrocyte micronucleus test (in viv /) e: Intravenous injection
Benzy	yl alcohol:			
-	toxicity in vitro		Type: Bacte lt: negative	rial reverse mutation assay (AMES)
Genot	toxicity in vivo	cytog Speci Applio	enetic assa es: Mouse	nalian erythrocyte micronucleus test (in viv /) :: Intraperitoneal injection
	nogenicity assified based on av	ailable inform	ation	
	oonents:			
	amicin:			
	nogenicity - Assess-	: No da	ata available	
Benzy	yl alcohol:			
Speci		: Mous	~	



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	Application Route Exposure time Method Result		 Ingestion 103 weeks OECD Test Guideline 451 negative 					
	•	uctive toxicity nage the unborn child						
	<u>Compo</u>	nents:						
	Gentam							
	Effects of	on fertility	:	Species: Rat Fertility: NOAEL: 2	eneration reproduction toxicity study 20 mg/kg body weight ant adverse effects were reported			
	Effects of ment	on foetal develop-	:	Species: Rabbit	o-foetal development xicity: NOAEL: 3.6 mg/kg body weight o-foetal toxicity			
				Species: Rat Application Route	xicity: LOAEL: 75 mg/kg body weight			
				Species: Mouse Application Route Developmental To	o-foetal development Intraperitoneal exicity: LOAEL: 10 mg/kg body weight tality, No malformations were observed.			
				Species: Rat Application Route: Developmental To	o-foetal development Intraperitoneal exicity: LOAEL: 50 mg/kg body weight tality, No malformations were observed.			
	Reprodu sessme	uctive toxicity - As- nt	:	Positive evidence human epidemiolo	of adverse effects on development from ogical studies.			
	Benzyl	alcohol:						
	-	on fertility	:	Species: Rat Application Route Result: negative	 /early embryonic development Ingestion on data from similar materials 			
	Effects of ment	on foetal develop-	:	Test Type: Embry Species: Mouse Application Route Result: negative	o-foetal development			



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	- single exposure assified based on avai	able information.
STOT	- repeated exposure	
	ause damage to orgar	s (Kidney, inner ear) through prolonged or repeated exposure if
Comp	oonents:	
Genta	amicin:	
	t Organs ssment	 Kidney, inner ear Causes damage to organs through prolonged or repeated exposure.
Repea	ated dose toxicity	
Comp	oonents:	
Genta	amicin:	
Expos	L cation Route sure time t Organs	 Dog 3 mg/kg Intramuscular 12 Months Kidney Vomiting, Salivation
Expos		 Monkey 50 mg/kg Subcutaneous 3 Weeks Kidney, inner ear
Expos		 Monkey 6 mg/kg Intramuscular 3 Weeks Blood, Kidney, inner ear, Liver
Expos	EL	: Rat : 5 mg/kg : 10 mg/kg : Intramuscular : 52 Weeks : Kidney, Blood
Expos	EL	: Rat : 12.5 mg/kg : 50 mg/kg : Intramuscular : 13 Weeks : Kidney
Benzy Specie	yl alcohol: es	: Rat



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Appl Expo	NOAEL:Application Route:Exposure time:Method:		1.072 mg/l inhalation (dust/mist/fume) 28 Days OECD Test Guideline 412			
-	iration toxicity classified based on availa	ıble	information.			
Exp	erience with human exp	osı	ire			
Com	ponents:					
Gen	tamicin:					
Inge	stion	:	Target Organs: Ki Target Organs: in Symptoms: Dizzir deafness			
Section '	12: Ecological information	on				
Eco	toxicity					
	-					
	iponents:					
Toxi	tamicin: city to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te			
			LC50 (Americamy Exposure time: 96 Method: US-EPA			
Toxi plan	city to algae/aquatic ts	:	EC50 (Pseudokiro Exposure time: 72 Method: OECD Te			
			NOEC (Pseudokin µg/l Exposure time: 72 Method: OECD Te			
			EC50 (Anabaena Exposure time: 72 Method: OECD Te			
			NOEC (Anabaena Exposure time: 72 Method: OECD To			
Toxi	city to microorganisms	:	EC50: 288.7 mg/l Exposure time: 3 Test Type: Respir Method: OECD To	h ration inhibition		



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Benzy	yl alcohol:			
-	ty to fish	:	LC50 (Pimephale Exposure time: 90	s promelas (fathead minnow)): 460 mg/l 5 h
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 44 Method: OECD T	
Toxici plants	ty to algae/aquatic	:	EC50 (Pseudokin mg/l Exposure time: 72 Method: OECD T	
			NOEC (Pseudoki mg/l Exposure time: 72 Method: OECD T	
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia) Exposure time: 2 Method: OECD T	
Persis	stence and degradabili	ty		
<u>Comp</u>	oonents:			
Genta	amicin:			
Biode	gradability	:	Result: rapidly de Biodegradation: Exposure time: 24 Method: OECD T	100 % 3 d
Benzy	yl alcohol:			
-	gradability	:	Result: Readily b Biodegradation: Exposure time: 14	92 - 96 %
Bioac	cumulative potential			
Comp	oonents:			
Partiti	amicin: on coefficient: n- ol/water	:	log Pow: < -2	
Partiti	yl alcohol: on coefficient: n- ol/water	:	log Pow: 1.05	
	ity in soil ta available			
	adverse effects ta available			



/ersion .6	Revision Date: 10.10.2020		S Number: 5023-00007	Date of last issue: 13.09.2019 Date of first issue: 25.07.2017
ection 1	3: Disposal considerat	ions		
	·			
-	osal methods			
	e from residues aminated packaging	:	Empty contained dling site for re	ccordance with local regulations. ers should be taken to an approved waste ha cycling or disposal. e specified: Dispose of as unused product.
ection 1	4: Transport information	on		
Inter	national Regulations			
UNR	TDG			
	umber	:	UN 3082	
Prope	er shipping name		ENVIRONMEN N.O.S. (Gentamicin)	ITALLY HAZARDOUS SUBSTANCE, LIQUII
Class	3	:	9 ´	
	ing group	:		
Labe	Is	:	9	
ΙΑΤΑ	-DGR			
UN/I			UN 3082	
-	er shipping name		(Gentamicin)	y hazardous substance, liquid, n.o.s.
Class			9	
	ing group	-	III Miscellaneous	
Labe	ing instruction (cargo		964	
aircra		•	304	
Pack	ing instruction (passen- ircraft)	:	964	
	onmentally hazardous	:	yes	
IMDO	G-Code			
	umber	:	UN 3082	
Prope	er shipping name		ENVIRONMEN N.O.S. (Gentamicin)	ITALLY HAZARDOUS SUBSTANCE, LIQUI
Class	3		9	
	ing group		111	
Labe	-		9	
	Code ne pollutant		F-A, S-F ves	
	•		•	
	pplicable for product as	-		RPOL 73/78 and the IBC Code
Natio	onal Regulations			
NZS	5/133			
	umber	÷	UN 3082	
	er shipping name	:		ITALLY HAZARDOUS SUBSTANCE, LIQUI

N.O.S. (Gentamicin)

: 9Ì

Class



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Labels	ng group em Code	: III : 9 : 3Z	

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

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls

Certified handler certificate not required. Tracking hazardous substance not required. Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

Section 16: Other information

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



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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; 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