

### **Gentamicin Cream Formulation**

Vers 2.2	ion	Revision Date: 09.04.2021		S Number: 4914-00009	Date of last issue: 10.10.2020 Date of first issue: 21.07.2017				
1. PI	RODUC	T AND COMPANY IDE	ENT	IFICATION					
	Produc	t name	:	Gentamicin Cream Formulation					
	Manufa	acturer or supplier's d	etai	ls					
	Compa	iny	:	Organon & Co.					
	Addres	S	:	30 Hudson Stree Jersey City, New	t, 33nd floor Jersey, U.S.A 07302				
	Teleph	one	:	551-430-6000					
	Emerge	ency telephone number	:	215-631-6999					
	E-mail	address	:	EHSSTEWARD@	⊉organon.com				
	Recom	mended use of the ch	om	ical and restrictio					
		mended use	:						
2. H	AZARD	S IDENTIFICATION							
	GHS C	lassification							
	Reprod	luctive toxicity	:	Category 1A					
		c target organ toxicity - ed exposure (Oral)	:	Category 2 (Kidn	ey, inner ear)				
	Short-te hazard	erm (acute) aquatic	:	Category 1					
		<b>ibel elements</b> I pictograms	:		¥_2				
	Signal	word	:	Danger	V				

Hazard statements : H360D May damage the unborn child. H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed. H400 Very toxic to aquatic life.

 Precautionary statements
 :
 Prevention:

 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.

 P260 Do not breathe vapours.
 P260 Do not breathe vapours.

 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.



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		<b>Response:</b> P308 + P313 I attention. P391 Collect s	F exposed or concerned: Get medical advice/

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

# Other hazards which do not result in classification

None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Propylene glycol monostearate	1323-39-3	10
Polyethylene Glycol Sorbitan Monostearate	9005-67-8	6
Stearic acid	57-11-4	6
Gentamicin	1403-66-3	1

#### 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	:	
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed Protection of first-aiders	:	May damage the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.
Notes to physician	:	and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively.



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5. FIREFIC	GHTING MEASURES					
Suitat	ble extinguishing media	: Water spray Alcohol-resist Carbon dioxid Dry chemical				
Unsui media	table extinguishing	: None known.				
Speci fightin	fic hazards during fire-	: Exposure to c	ombustion products may be a hazard to health.			
	dous combustion prod-	: Carbon oxide	S			
Speci ods	fic extinguishing meth-	cumstances a Use water spr				
	al protective equipment efighters	: In the event o	f fire, wear self-contained breathing apparatus. protective equipment.			
6. ACCIDE	ENTAL RELEASE MEAS	SURES				
tive e	nal precautions, protec- quipment and emer- procedures	Follow safe ha	protective equipment. andling advice (see section 7) and personal pro- nent recommendations (see section 8).			
Enviro	onmental precautions	Prevent furthe Prevent sprea barriers). Retain and dis	to the environment. er leakage or spillage if safe to do so. Iding over a wide area (e.g. by containment or oil spose of contaminated wash water. ies should be advised if significant spillages itained.			
	ods and materials for inment and cleaning up	For large spill ment to keep be pumped, s Clean up rem bent. Local or natio posal of this n employed in t mine which re Sections 13 a	inert absorbent material. s, provide dyking or other appropriate contain- material from spreading. If dyked material can tore recovered material in appropriate container. aining materials from spill with suitable absor- nal regulations may apply to releases and dis- naterial, as well as those materials and items he cleanup of releases. You will need to deter- gulations are applicable. nd 15 of this SDS provide information regarding r national requirements.			

#### 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



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ļ	Advice on safe handling		Handle in accord practice, based sessment Keep container t Do not eat, drink		vapours. /ith eyes. oughly after handling. rdance with good industrial hygiene and safety on the results of the workplace exposure as-				
(	Conditions for safe storage		environment. : Keep in properly labelled containers. Store locked up. Keep tightly closed.						
Materials to avoid			:	Store in accordan	ce with the particular national regulations. the following product types:				

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type	Control parame-	Basis
Componenta	0/10/110.	(Form of	ters / Permissible	Dabio
		exposure)	concentration	
Propylene glycol monostearate	1323-39-3	PEL (long	10 mg/m3	SG OEL
		term)	1 0g,o	
		TWA (Inhal-	10 mg/m3	ACGIH
		able particu-		
		late matter)		
		TWA (Res-	3 mg/m3	ACGIH
		pirable par-		
		ticulate mat-		
		ter)		
Polyethylene Glycol Sorbitan	9005-67-8	PEL (long	10 mg/m3	SG OEL
Monostearate		term)		
		TWA (Inhal-	10 mg/m3	ACGIH
		able particu-		
		late matter)		
		TWA (Res-	3 mg/m3	ACGIH
		pirable par-		
		ticulate mat-		
		ter)		
Stearic acid	57-11-4	TWA (Inhal-	10 mg/m3	ACGIH
		able particu-		
		late matter)		
		TWA (Res-	3 mg/m3	ACGIH
		pirable par-		
		ticulate mat-		
		ter)		
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB	Internal
			2)	

### Components with workplace control parameters



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Enç	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.		
Per	sonal protective equipn	nent			
	Respiratory protection Filter type		If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Combined particulates and organic vapour type		
	Hand protection Material		Chemical-resistar	nt gloves	
Eye	Eye protection		If the work enviro mists or aerosols. Wear a faceshield	ses with side shields or goggles. Inment or activity involves dusty conditions, wear the appropriate goggles. If or other full face protection if there is a t contact to the face with dusts, mists, or	
	n and body protection jiene measures	:	Work uniform or la If exposure to che eye flushing syste ing place. When using do no Wash contaminat The effective ope engineering contr appropriate dego	emical is likely during typical use, provide ems and safety showers close to the work- ot eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, wning and decontamination procedures, monitoring, medical surveillance and the	

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	cream
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available



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	Flamma	ability (solid, gas)	:	Not applicable	
	Flammability (liquids) Upper explosion limit / Upper flammability limit		:	No data available	
			:	No data available	
		explosion limit / Lower bility limit	:	No data available	)
	Vapour	pressure	:	No data available	
	Relative	e vapour density	:	No data available	
	Relative	edensity	:	No data available	)
	Density		:	No data available	)
	Solubilit Wate	ty(ies) er solubility	:	No data available	9
		n coefficient: n-	:	No data available	)
	octanol/ Auto-igr	nition temperature	:	No data available	)
	Decomp	position temperature	:	No data available	)
	Viscosit Visc	y osity, kinematic	:	No data available	)
	Explosiv	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	r mixture is not classified as oxidizing.
	Molecul	ar weight	:	No data available	9
	Particle	size	:	No data available	)

#### **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.

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation



sion	Revision Date: 09.04.2021		S Number: 44914-00009	Date of last issue: 10.10.2020 Date of first issue: 21.07.2017		
exposure			Skin contact Ingestion Eye contact			
Acute	e toxicity					
Not cl	assified based on avai	lable	information.			
<u>Comp</u>	oonents:					
Propy	lene glycol monoste	arate	:			
Acute	oral toxicity	:	LD50 (Mouse):	> 5,000 mg/kg		
Polye	thylene Glycol Sorbit	tan N	lonostearate:			
Acute	oral toxicity	:	LD50 (Mouse):	> 15,000 mg/kg		
Stear	ic acid:					
Acute	oral toxicity	:	LD50 (Rat): > 5 Method: OECD	,000 mg/kg Test Guideline 401		
Acute	inhalation toxicity	:	LC50 (Rat): > 2 Exposure time: Test atmospher Remarks: Base	1 h		
Acute	dermal toxicity	:	LD50 (Rabbit): Assessment: Th toxicity	> 2,000 mg/kg ne substance or mixture has no acute derm		
Genta	amicin:					
Acute	oral toxicity	:	LD50 (Rat): 8,0	00 - 10,000 mg/kg		
			LD50 (Mouse):	10,000 mg/kg		
Acute	inhalation toxicity	:	LC50 (Rat): > 0 Exposure time: Test atmospher Remarks: No m	4 h		
	toxicity (other routes c istration)	of :	LD50 (Rat): 67 Application Rou			
			LD50 (Rat): 371 Application Rou	- 384 mg/kg te: Intramuscular		
			LDLo (Monkey) Application Rou			

Not classified based on available information.

### Components:

Propylene glycol monostearate:



ersion 2	Revision Date: 09.04.2021	SDS Number: 1844914-00009	Date of last issue: 10.10.2020 Date of first issue: 21.07.2017
Resul	t	: No skin irritation	
Stear	ic acid:		
Speci	es	: Rabbit	
Metho		: Patch Test 24 H	
Resul	t	: No skin irritation	
Genta	amicin:		
Speci		: Rabbit	
Resul	t	: Mild skin irritatio	n
Serio	us eye damage/eye	irritation	
Not cl	assified based on av	ailable information.	
<u>Com</u>	oonents:		
	ic acid:	D. L. Y	
Speci Resul		: Rabbit : No eye irritation	
Ocat	miain		
	amicin:	. D.111	
Speci Resul		: Rabbit : Mild eye irritatio	n
Resp	iratory or skin sens	itisation	
Skin	sensitisation		
Not cl	assified based on av	ailable information.	
Resp	iratory sensitisatior	1	
-	assified based on av		
<u>Comp</u>	oonents:		
Stear	ic acid:		
Test		: Maximisation Te	est
	sure routes	: Skin contact	
Speci Resul		: Guinea pig : negative	
Rema		: Based on data f	rom similar materials
Genta	amicin:		
Rema		: No data availab	e
Germ	cell mutagenicity		
	assified based on av	ailable information.	
<u>Com</u>	oonents:		
Stear	ic acid:		



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			Result: negative	est Guideline 473 on data from similar materials
			Method: OECD T Result: negative	o mammalian cell gene mutation test est Guideline 476 on data from similar materials
			Result: negative	rial reverse mutation assay (AMES) on data from similar materials
Gent	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 /) e: Intravenous injection
	nogenicity lassified based on availa	ble	information.	
<u>Com</u>	oonents:			
	<b>amicin:</b> nogenicity - Assess-	:	No data available	
-	oductive toxicity damage the unborn child			
Com	oonents:			
Stear	ic acid:			
Effect	s on fertility	:	reproduction/deve Species: Rat Application Route Method: OECD T Result: negative	ined repeated dose toxicity study with the elopmental toxicity screening test e: Ingestion est Guideline 422 on data from similar materials
Effect ment	s on foetal develop-	:	reproduction/deve Species: Rat Application Route	ined repeated dose toxicity study with the elopmental toxicity screening test e: Ingestion est Guideline 422



ersion .2	Revision Date: 09.04.2021	SDS Number:Date of last issue: 10.10.20201844914-00009Date of first issue: 21.07.2017
		Remarks: Based on data from similar materials
Gent	amicin:	
	ts on fertility	<ul> <li>Test Type: Two-generation reproduction toxicity study Species: Rat Fertility: NOAEL: 20 mg/kg body weight Result: No significant adverse effects were reported</li> </ul>
Effect ment	ts on foetal develop-	<ul> <li>Test Type: Embryo-foetal development Species: Rabbit Developmental Toxicity: NOAEL: 3.6 mg/kg body weight Result: No embryo-foetal toxicity</li> </ul>
		Test Type: Embryo-foetal development Species: Rat Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 75 mg/kg body weight Result: Embryo-foetal toxicity
		Test Type: Embryo-foetal development Species: Mouse Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: foetal mortality, 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 observed.
Repro sessr	oductive toxicity - As- nent	: Positive evidence of adverse effects on development from human epidemiological studies.
	<b>Γ - single exposure</b> lassified based on avai	lable information.
May o	F - repeated exposure cause damage to orgar owed.	ns (Kidney, inner ear) through prolonged or repeated exposure if
Com	ponents:	
Gent	amicin:	
	et Organs ssment	<ul> <li>Kidney, inner ear</li> <li>Causes damage to organs through prolonged or repeated exposure.</li> </ul>
Repe	ated dose toxicity	
Com	ponents:	
<b>Stear</b> Speci	<b>ic acid:</b> ies	: Rat





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	ation Route sure time od	<ul> <li>1,000 mg/kg</li> <li>Ingestion</li> <li>42 Days</li> <li>OECD Test Guideline 422</li> <li>Based on data from similar materials</li> </ul>
Specie LOAE Applic Expos Targe Symp Specie LOAE Applic Expos Targe Specie LOAE	L cation Route sure time t Organs toms es L cation Route sure time t Organs es	<ul> <li>Dog</li> <li>3 mg/kg</li> <li>Intramuscular</li> <li>12 Months</li> <li>Kidney</li> <li>Vomiting, Salivation</li> <li>Monkey</li> <li>50 mg/kg</li> <li>Subcutaneous</li> <li>3 Weeks</li> <li>Kidney, inner ear</li> <li>Monkey</li> <li>6 mg/kg</li> <li>Intramuscular</li> </ul>
Expos	sure time t Organs	: 3 Weeks : Blood, Kidney, inner ear, Liver
Expos	EL	<ul> <li>Rat</li> <li>5 mg/kg</li> <li>10 mg/kg</li> <li>Intramuscular</li> <li>52 Weeks</li> <li>Kidney, Blood</li> </ul>
Expos	EL	<ul> <li>Rat</li> <li>12.5 mg/kg</li> <li>50 mg/kg</li> <li>Intramuscular</li> <li>13 Weeks</li> <li>Kidney</li> </ul>
Not cl	ation toxicity assified based on ava	
Expe	rience with human e>	posure
<u>Comp</u>	oonents:	
Genta Ingest	amicin: tion	: Target Organs: Kidney Target Organs: inner ear Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness



ersion 2	Revision Date: 09.04.2021		9S Number: 44914-00009	Date of last issue: 10.10.2020 Date of first issue: 21.07.2017			
2. ECOL	ECOLOGICAL INFORMATION						
Ecote	oxicity						
Com	ponents:						
Polye	ethylene Glycol Sorbita	n M	onostearate:				
Toxic plants	ity to algae/aquatic s	:	EC50: > 10 - 100 Exposure time: 72 Remarks: Based o				
Stear	ric acid:						
Toxic	to fish	:	LL50 (Leuciscus id Exposure time: 48 Method: DIN 3841				
	ity to daphnia and other tic invertebrates	:	Exposure time: 48 Method: OECD Te	est Guideline 202 on data from similar materials			
Toxic plants	ty to algae/aquatic s	:	mg/l Exposure time: 72 Method: OECD Te	est Guideline 201 on data from similar materials			
			mg/l Exposure time: 72 Method: OECD Te	est Guideline 201 on data from similar materials			
	ity to daphnia and other tic invertebrates (Chron- icity)	:	Exposure time: 21 Method: OECD Te	est Guideline 211 on data from similar materials			
Toxic	ity to microorganisms	:	EC10 (Pseudomo Exposure time: 18	nas putida): 883 mg/l h			
Gent	amicin:						
	ity to daphnia and other tic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	agna (Water flea)): 86 mg/l h est Guideline 202			
			LC50 (Americamy Exposure time: 96 Method: US-EPA	5 h			



rsion	Revision Date: 09.04.2021	-	9S Number: 44914-00009	Date of last issue: 10.10.2020 Date of first issue: 21.07.2017
Toxic plants	ity to algae/aquatic	:	Exposure time: 7	rchneriella subcapitata (green algae)): 10 μg /2 h Γest Guideline 201
			µg/l Exposure time: 7	irchneriella subcapitata (green algae)): 1.5 ′2 h Fest Guideline 201
			Exposure time: 7	a flos-aquae (cyanobacterium)): 4.7 μg/l ′2 h Γest Guideline 201
			Exposure time: 7	na flos-aquae (cyanobacterium)): 1.6 μg/l ′2 h Γest Guideline 201
	ctor (Acute aquatic tox-	:	100	
icity) M-Factor (Chronic aquatic		:	1	
toxicit Toxic	ty) ity to microorganisms	:	EC50: 288.7 mg Exposure time: 3 Test Type: Resp Method: OECD	3 h
Persi	stence and degradabil	ity		
<u>Com</u>	oonents:			
-	ethylene Glycol Sorbita	In M		
Blode	gradability			ily biodegradable. on data from similar materials
Stear	ic acid:			
Biode	ic aciu.			
	egradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD	71 %
		:	Biodegradation: Exposure time: 2	71 % 28 d
Genta	egradability	:	Biodegradation: Exposure time: 2 Method: OECD Result: rapidly de Biodegradation: Exposure time: 2	71 % 28 d Fest Guideline 301B egradable 100 %
<b>Gent</b> a Biode	amicin:	:	Biodegradation: Exposure time: 2 Method: OECD Result: rapidly de Biodegradation: Exposure time: 2	71 % 28 d Fest Guideline 301B egradable 100 % 28 d
Genta Biode Bioac	amicin: egradability	:	Biodegradation: Exposure time: 2 Method: OECD Result: rapidly de Biodegradation: Exposure time: 2	71 % 28 d Fest Guideline 301B egradable 100 % 28 d
Genta Biode Bioac <u>Comp</u> Stear	egradability amicin: egradability ccumulative potential	:	Biodegradation: Exposure time: 2 Method: OECD Result: rapidly de Biodegradation: Exposure time: 2	71 % 28 d Fest Guideline 301B egradable 100 % 28 d



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octan	ol/water			
Genta	amicin:			
	on coefficient: n-		log Pow: < -2	
	ol/water	•	1091 000. < 2	
Mobil	ity in soil			
Mobility in soil No data available				
	adverse effects			
No da	ta available			
3. DISPO	SAL CONSIDERATIO	NS		
Dispo	osal methods			
Waste	e from residues	:		cordance with local regulations.
Conta	minated packaging	:		rs should be taken to an approved waste han
				cycling or disposal.
			ii not otherwise	specified: Dispose of as unused product.
4. TRAN	SPORT INFORMATION	I		
Interr	national Regulations			
UNR	TDG			
	umber	:	UN 3082	
Prope	er shipping name	:	ENVIRONMEN <sup>®</sup>	TALLY HAZARDOUS SUBSTANCE, LIQUID
			N.O.S.	
			(Gentamicin) 9	
Class			J	
Class Packi				
	ng group	:	III 9	
Packi Label	ng group s	:	III	
Packi Label <b>IATA</b> -	ng group s • <b>DGR</b>	:	 9	
Packi Label <b>IATA</b> - UN/ID	ng group s • <b>DGR</b>		III 9 UN 3082 Environmentally	v hazardous substance, liquid, n.o.s.
Packi Label IATA UN/ID Prope	ng group s • <b>DGR</b> 9 No. er shipping name		III 9 UN 3082 Environmentally (Gentamicin)	hazardous substance, liquid, n.o.s.
Packi Label IATA UN/IE Prope Class	ng group s • <b>DGR</b> 9 No. •r shipping name	· · · · · · · · · · · · · · · · · · ·	III 9 UN 3082 Environmentally (Gentamicin) 9	hazardous substance, liquid, n.o.s.
Packi Label IATA- UN/IE Prope Class Packi	ng group s • <b>DGR</b> 9 No. •r shipping name ng group		III 9 UN 3082 Environmentally (Gentamicin) 9 III	r hazardous substance, liquid, n.o.s.
Packi Label IATA- UN/IE Prope Class Packi Label	ng group s • <b>DGR</b> 9 No. •r shipping name ng group		III 9 UN 3082 Environmentally (Gentamicin) 9	hazardous substance, liquid, n.o.s.
Packi Label IATA UN/IE Prope Class Packi Label Packi aircra	ng group s • <b>DGR</b> ) No. er shipping name ng group s ng instruction (cargo ft)		III 9 UN 3082 Environmentally (Gentamicin) 9 III Miscellaneous 964	<sup>,</sup> hazardous substance, liquid, n.o.s.
Packi Label IATA UN/IE Prope Class Packi Label Packi aircra Packi	ng group s • <b>DGR</b> • No. •r shipping name ng group s ng instruction (cargo ft) ng instruction (passen-		III 9 UN 3082 Environmentally (Gentamicin) 9 III Miscellaneous	r hazardous substance, liquid, n.o.s.
Packi Label IATA UN/IE Prope Class Packi Label Packi aircra Packi ger ai	ng group s • <b>DGR</b> • No. •r shipping name ng group s ng instruction (cargo ft) ng instruction (passen- rcraft)		III 9 UN 3082 Environmentally (Gentamicin) 9 III Miscellaneous 964 964	hazardous substance, liquid, n.o.s.
Packi Label IATA UN/IE Prope Class Packi Label Packi aircra Packi ger ai Enviro	ng group s •DGR ) No. er shipping name ng group s ng instruction (cargo ft) ng instruction (passen- rcraft) onmentally hazardous		III 9 UN 3082 Environmentally (Gentamicin) 9 III Miscellaneous 964	r hazardous substance, liquid, n.o.s.
Packi Label IATA UN/IE Prope Class Packi Label Packi aircra Packi ger ai Enviro	ng group s •DGR •No. •r shipping name ng group s ng instruction (cargo ft) ng instruction (passen- rcraft) onmentally hazardous • <b>-Code</b>		III 9 UN 3082 Environmentally (Gentamicin) 9 III Miscellaneous 964 964 yes	r hazardous substance, liquid, n.o.s.
Packi Label IATA UN/IE Prope Class Packi Label Packi aircra Packi ger ai Enviro IMDG UN nu	ng group s •DGR •No. •r shipping name ng group s ng instruction (cargo ft) ng instruction (passen- rcraft) onmentally hazardous • <b>-Code</b> umber		III 9 UN 3082 Environmentally (Gentamicin) 9 III Miscellaneous 964 964 964 yes UN 3082	
Packi Label IATA UN/IE Prope Class Packi Label Packi aircra Packi ger ai Enviro IMDG UN nu	ng group s •DGR •No. •r shipping name ng group s ng instruction (cargo ft) ng instruction (passen- rcraft) onmentally hazardous • <b>-Code</b>		III 9 UN 3082 Environmentally (Gentamicin) 9 III Miscellaneous 964 964 964 yes UN 3082	
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#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### 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.

#### **15. REGULATORY INFORMATION**

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazard- ous Substances) Regulations	:	Not applicable	
Fire Safety (Petroleum and Flammable Materials)	:	Not applicable	

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

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

#### **16. OTHER INFORMATION**

Regulations

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 abbreviation		
ACGIH SG OEL		USA. ACGIH Threshold Limit Values (TLV) Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances
ACGIH / TWA SG OEL / PEL (long term)	:	8-hour, time-weighted average Permissible Exposure Level (PEL) Long Term

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 -



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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; 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.

SG / EN