SAFETY DATA SHEET



Tulathromycin Formulation

Version	Revision Date: 2023/09/30	SDS Number:	Date of last issue: 2023/04/04
7.0		5297463-00010	Date of first issue: 2019/11/13

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Tulathromycin Formulation
Supplier's company name, ad Company name of supplier		ess and phone number MSD
Address	:	Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone	:	048-588-8411
E-mail address	:	EHSDATASTEWARD@msd.com
Emergency telephone number	:	+1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

Skin corrosion/irritation	:	Category 2
Serious eye damage/eye irri- tation	:	Category 1
Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Liver, Eye)
Short-term (acute) aquatic hazard	:	Category 1
Long-term (chronic) aquatic hazard	:	Category 1
GHS label elements Hazard pictograms	:	





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Signa	l word	: Danger				
Hazard statements		H317 May caus H318 Causes s H361 Suspecte H372 Causes o or repeated exp	 H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H361 Suspected of damaging fertility or the unborn child. H372 Causes damage to organs (Liver, Eye) through prolonge or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting effects. 			
Precautionary statements		P202 Do not ha and understood P260 Do not br P264 Wash ski P270 Do not ea P272 Contamir the workplace. P273 Avoid rele	eathe mist or vapours. n thoroughly after handling. at, drink or smoke when using this product. nated work clothing should not be allowed out o ease to the environment. tective gloves/ protective clothing/ eye protec-			
		P305 + P351 + water for sever and easy to do CENTER/ docto P308 + P313 IF attention. P333 + P313 If vice/ attention.	exposed or concerned: Get medical advice/ skin irritation or rash occurs: Get medical ad- ake off contaminated clothing and wash it before			
		Storage: P405 Store loc	ked up.			
		Disposal: P501 Dispose o disposal plant.	of contents/ container to an approved waste			
None	r hazards which do no known.					

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture



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Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Propylene glycol	57-55-6	>= 50 - < 60	2-234
Tulathromycin	217500-96-4	>= 10 - < 20	
Hydrochloric acid	7647-01-0	>= 3 - < 5	1-215
Citric acid	77-92-9	>= 1 - < 10	2-1318
Sodium hydroxide	1310-73-2	>= 1 - < 2	1-410
3-Mercaptopropane-1,2-diol	96-27-5	>= 0.1 - < 1	9-805

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 plenty of water for at least 15 minutes while removing 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	:	Causes skin irritation. May cause an allergic skin reaction. Causes serious eye damage. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated
Protection of first-aiders	:	exposure if swallowed. 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



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Uns	suitable extinguishing dia	:	Carbon dioxide (C Dry chemical None known.	CO2)	
figh	ecific hazards during fire- iting zardous combustion prod- s	:	Exposure to comb Carbon oxides Chlorine compour Metal oxides	bustion products may be a hazard to health.	
•	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. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.		
	Special protective equipment for firefighters		In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.		
6. ACCI	DENTAL RELEASE MEAS	SUF	RES		
tive	rsonal precautions, protec- equipment and emer- ncy procedures	:	Follow safe handl	ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).	
Env	Environmental 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	
	thods and materials for ntainment and cleaning up	:	For large spills, pument to keep mat be pumped, store Clean up remaining bent. Local or national uposal of this mate employed in the of mine which regula Sections 13 and 1	t absorbent material. rovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. ng 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. HANDLING AND STORAGE

Handling

Technical measures	: See Engineering measures under EXPOSURE
	CONTROLS/PERSONAL PROTECTION section.



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Advid	cal/Total ventilation: Use only with adedvice on safe handling: Do not get on skidvice on safe handling: Do not breatherDo not swallow.Do not swallow.Do not get in eyeWash skin thorouHandle in accordpractice, based osessmentKeep container tiDo not eat, drinkTake care to prevenvironment.voidance of contact//giene measures: If exposure to charflushing systemsplace.When using do nContaminated woworkplace.Wash contaminaThe effective opeengineering contraappropriate degoindustrial hygiene		Do not get in eyes Wash skin thorou Handle in accords practice, based o sessment Keep container tig Do not eat, drink Take care to prevenvironment. Oxidizing agents If exposure to che flushing systems place. When using do not Contaminated wo workplace. Wash contaminat The effective ope engineering contr appropriate dego	n or clothing. ist or vapours. s. ghly after handling. ance with good industrial hygiene and safety in the results of the workplace exposure as- ghtly closed. or smoke when using this product. rent spills, waste and minimize release to the emical is likely during typical use, provide eye and safety showers close to the working of eat, drink or smoke. rk clothing should not be allowed out of the red clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, wning and decontamination procedures, emonitoring, medical surveillance and the
Stora	-			
	litions for safe storage rials to avoid	:	Store locked up. Keep tightly close Store in accordar	ce with the particular national regulations. the following product types:
Pack	aging material	:	Unsuitable mater	al: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work en-
vironment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Reference concentration / Permissible con- centration	Basis		
Tulathromycin	217500-96-4	TWA	300 µg/m3 (OEB 2)	Internal		
	Further information: DSEN					
		Wipe limit	100 µg/100 cm2	Internal		
Hydrochloric acid	7647-01-0	OEL-C	2 ppm 3 mg/m3	JP OEL JSOH		



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		С	2 ppm	ACGIH			
Sodium hydroxide	1310-73	-2 OEL-C	2 mg/m3	JP OEL			
				JSOH			
		С	2 mg/m3	ACGIH			
Engineering measures	design a protect Essentia Use clo If handle cabinet tial exis	All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the poten- tial exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.					
Personal protective equipm		over lined trays of	benchiops.				
Respiratory protection	: If adequ sure as	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 acidic gas/vapour type					
Material	: Chemic	Chemical-resistant gloves					
Remarks Eye protection	: Wear sa If the we mists or Wear a potentia	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.					
Skin and body protection	: Work ur Additior task bei posable Use app	niform or laborato nal body garments ng performed (e.g suits) to avoid ex	ry coat. s should be used bas g., sleevelets, apron, xposed skin surfaces ng techniques to rem	gauntlets, dis-			

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: liquid
Colour	: Colorless to pale yellow
Odour	: slight
Odour Threshold	: No data available
Melting point/freezing point	: 190 - 192 °C
Boiling point, initial boiling point and boiling range	: No data available

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F	Flammat	pility (solid, gas)	:	Not applicable	
F	Flammat	pility (liquids)	:	No data available)
L	Upper	plosion limit and uppe r explosion limit / Up- ammability limit			
		r explosion limit / r flammability limit	:	No data available	
F	Flash poi	int	:	No data available)
[Decompo	osition temperature	:	No data available)
ŗ	рH		:	5.1 - 5.7	
E	Evaporat	tion rate	:	No data available	9
ļ	Auto-igni	tion temperature	:	No data available	
١	Viscosity Visco	sity, kinematic	:	No data available	9
ç	Solubility Water	r(ies) r solubility	:	> 1,000 mg/l	
	Partition octanol/w	coefficient: n- vater	:	log Pow: -1.41	
١	Vapour p	pressure	:	No data available)
[and / or relative densit ive density	iy :	No data available	
	Densi	ity	:	1.07 g/cm ³	
F	Relative	vapour density	:	No data available)
E	Explosive	e properties	:	Not explosive	
(Oxidizing	properties	:	The substance or	mixture is not classified as oxidizing.
ſ	Molecula	ır weight	:	806.09 g/mol	
F		characteristics le size	:	Not applicable	



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Possi tions Cond Incon	nical stability ibility of hazardous reac- litions to avoid npatible materials rdous decomposition		Stable under no Can react with s None known. Oxidizing agent	s a reactivity hazard. ormal conditions. strong oxidizing agents. s lecomposition products are known.
11. TOXIC	OLOGICAL INFORMA	τιο	N	
Inforr expos	nation on likely routes of sure	f:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	able	information.	
Prod Acute	uct: inhalation toxicity	:	Acute toxicity es Exposure time: 4 Test atmosphere Method: Calcula	4 h e: dust/mist
Acute	e dermal toxicity	:	Acute toxicity es Method: Calcula	timate: > 2,000 mg/kg tion method
<u>Com</u>	ponents:			
	ylene glycol:			
Acute	e oral toxicity	:	LD50 (Rat): 22,0	100 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 44 Exposure time: 4 Test atmosphere	1 h
Acute	e dermal toxicity	:	 LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute toxicity 	
Tulat	hromycin:			
Acute	e oral toxicity	:	LD50 (Dog): > 1 Target Organs: (,000 mg/kg Gastrointestinal tract
			LD50 (Rat): > 2, Target Organs: (000 mg/kg Gastrointestinal tract
Acute	e dermal toxicity	:	LD50 (Rabbit): > Target Organs: (2,000 mg/kg Gastrointestinal tract



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	ochloric acid: inhalation toxicity): 8.3 mg/l time: 30 min sphere: dust/mist			
II Citric	acid					
	oral toxicity	: LD50 (Mo	use): 5,400 mg/kg			
Acute	dermal toxicity	Method: C	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dern toxicity			
	ım hydroxide:					
Acute	inhalation toxicity	: Assessme	nt: Corrosive to the respiratory tract.			
	captopropane-1,2-d): 645 mg/kg			
Acute	inhalation toxicity	Exposure Test atmo): > 0.5 - 1 mg/l time: 4 h sphere: dust/mist Based on data from similar materials			
Acute	dermal toxicity	: LD50 (Rat	LD50 (Rabbit): 670 mg/kg			
	corrosion/irritation es skin irritation.					
<u>Comp</u>	oonents:					
Propy	/lene glycol:					
Speci Metho Resul	od	: Rabbit : OECD Tes : No skin irr	at Guideline 404 tation			
Tulat	hromycin:					
Speci Resul		: Rabbit : No skin irr	tation			
Hydro	ochloric acid:					
Speci Metho	es		reconstructed human epidermis (RhE)OECD Test Guideline 431			
Resul	t	: Corrosive	after 3 minutes or less of exposure			
Citric						



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Spec Metho Resu	od	:	Rabbit OECD Test Gui No skin irritatior	
Sodiu	um hydroxide:			
Resu	lt	:	Corrosive after	3 minutes or less of exposure
	rcaptopropane-1,2-d			
Spec Resu	ies It	:	Rabbit Skin irritation	
	ous eye damage/eye es serious eye damag		ion	
	ponents:) -		
Prop	ylene glycol:			
Spec Resu		:	Rabbit No eye irritation	
Metho		:	OECD Test Gui	
Tulat	hromycin:			
Spec Resu		:	Rabbit Irreversible effe	cts on the eye
Hydr	ochloric acid:			
Spec Metho		:	Bovine cornea OECD Test Gui	deline 437
Resu	lt	:	Irreversible effe	cts on the eye
Citric	acid:			
Spec	•.	:	Rabbit	reversing within 21 days
Resu Metho		:	OECD Test Gui	s, reversing within 21 days deline 405
Sodiu	um hydroxide:			
Resu Rema		:	Irreversible effe Based on skin o	
	rcaptopropane-1,2-d	iol:		
Spec Resu		:	Rabbit No eye irritation	
III 1650		•	NO EYE IMIANON	



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Resp	iratory or skin sensit	sation						
•••••	Skin sensitisation May cause an allergic skin reaction.							
-	Respiratory sensitisation Not classified based on available information.							
<u>Com</u>	Components:							
Test	sure routes	: Ski : Gu	ximisation Tes n contact inea pig jative	st				

Tulathromycin:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Assessment	:	May cause sensitisation by skin contact.
Test Type Exposure routes Species Assessment Result	:	Causes sensitisation.

Hydrochloric acid:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Test Type Exposure routes Species Method Result	: negative

Sodium hydroxide:

Test Type Exposure routes Result	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Result	:	negative

3-Mercaptopropane-1,2-diol:

Test Type Exposure routes	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Species Method	: OECD Test Guideline 406
Result Remarks	: positive
Remarks	: Based on data from similar materials
Assessment	: Probability or evidence of low to moderate skin sensitisation rate in humans

Germ cell mutagenicity

Not classified based on available information.



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Comp	oonents:		
Pron	/lene glycol:		
	toxicity in vitro	: Test Type: Ba Result: negativ	cterial reverse mutation assay (AMES) /e
			romosome aberration test in vitro D Test Guideline 473 /e
Geno	toxicity in vivo	cytogenetic as Species: Mous	se fute: Intraperitoneal injection
 Tulati	nromycin:		
	toxicity in vitro	: Test Type: Ba Result: negativ	cterial reverse mutation assay (AMES) /e
		Test Type: Ch Result: negativ	romosome aberration test in vitro /e
Geno	toxicity in vivo	: Test Type: Ma cytogenetic as Species: Rat Result: negativ	
	cell mutagenicity - sment	: Weight of evid cell mutagen.	ence does not support classification as a gerr
II Hvdro	ochloric acid:		
	toxicity in vitro	: Test Type: Sa assay (in vitro) Result: negativ	
Citric	acid:		
	toxicity in vitro	: Test Type: Ba Result: negativ	cterial reverse mutation assay (AMES) /e
		Test Type: in v Result: positiv	<i>v</i> itro micronucleus test e
		Test Type: Ba Result: negativ	cterial reverse mutation assay (AMES) /e
Geno	toxicity in vivo		tagenicity (in vivo mammalian bone-marrow st, chromosomal analysis)



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II		Result: negat	ive
II Carci	nogenicity		
	assified based on avai	ilable information.	
Comp	oonents:		
	/lene glycol:		
Speci		: Rat	
	cation Route	: Ingestion	
Expos	sure time	: 2 Years	
Resul	t	: negative	
Tulatl	hromycin:		
Carcir ment	nogenicity - Assess-	: No data avail	able
Hydro	ochloric acid:		
Speci		: Rat	
	cation Route	: Inhalation	
Resul	sure time t	: 128 weeks : negative	
Suspe	oductive toxicity ected of damaging ferti conents:	ility or the unborn ch	ild.
Suspe <u>Comp</u>	ected of damaging ferti	ility or the unborn ch	ild.
Suspe <u>Comp</u> Propy	ected of damaging ferti conents:	: Test Type: Tv	wo-generation reproduction toxicity study
Suspe <u>Comp</u> Propy	ected of damaging ferti ponents: ylene glycol:	: Test Type: Ty Species: Mou	wo-generation reproduction toxicity study
Suspe <u>Comp</u> Propy	ected of damaging ferti ponents: ylene glycol:	: Test Type: Ty Species: Mou	wo-generation reproduction toxicity study ise oute: Ingestion
Suspe <u>Comp</u> Propy Effect	ected of damaging ferti ponents: ylene glycol:	: Test Type: Ty Species: Mou Application R Result: negat	wo-generation reproduction toxicity study ise oute: Ingestion
Suspe <u>Comp</u> Propy Effect	ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility	: Test Type: To Species: Mou Application R Result: negat : Test Type: En Species: Mou	wo-generation reproduction toxicity study ise oute: Ingestion ive mbryo-foetal development ise
Suspe <u>Comp</u> Propy Effect	ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility	: Test Type: To Species: Mou Application R Result: negat : Test Type: En Species: Mou	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion
Suspe <u>Comp</u> Propy Effect Effect ment	ected of damaging ferti <u>conents:</u> ylene glycol: s on fertility s on foetal develop-	: Test Type: Ty Species: Mou Application R Result: negat : Test Type: En Species: Mou Application R	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion
Suspe Comp Propy Effect Effect ment	ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin:	 Test Type: Type: Type: Type: Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation 	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion
Suspe Comp Propy Effect Effect ment	ected of damaging ferti <u>conents:</u> ylene glycol: s on fertility s on foetal develop-	 Test Type: Type: Type: Type: Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation Test Type: Fe Species: Ration 	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive
Suspe Comp Propy Effect Effect ment	ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin:	 Test Type: Type: Type: Type: Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation Test Type: Fe Species: Rat Application R 	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral
Suspe Comp Propy Effect Effect ment	ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin:	 Test Type: Two Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation Test Type: Fe Species: Rat Application R Fertility: NOA 	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral EL: 100 mg/kg body weight
Suspe Comp Propy Effect Effect ment	ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin:	 Test Type: Two Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation Test Type: Fe Species: Rat Application R Fertility: NOA 	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral
Suspe Comp Propy Effect Effect ment Tulati	ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin:	 Test Type: Type: Type: Type: End Species: Mou Application R Result: negation Test Type: End Species: Mou Application R Result: negation Test Type: Fed Species: Rat Application R Fertility: NOA Result: No signature Test Type: End Species: End Species: Rat Application R Species: No Species: No Species: No Species: Rat Application R Species: No Species: No Species: Rat Application R Species: Rat Application R Species: Rat Application R Species: No Species: No Species: Rat Application R Species: No Species: No Species: Rat Application R Species: Rat Application R Species: Rat Application R Species: No Species: Rat Application R Species: Rat Application R	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral EL: 100 mg/kg body weight
Suspe Comp Propy Effect Effect ment Tulati	ected of damaging ferti <u>conents:</u> ylene glycol: s on fertility s on foetal develop- hromycin: s on fertility	 Test Type: Type: Type: Type: Experies: Mou Application R Result: negation Test Type: Experies: Mou Application R Result: negation Test Type: Fe Species: Rat Application R Fertility: NOA Result: No signal 	wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral EL: 100 mg/kg body weight gnificant adverse effects were reported mbryo-foetal development



ersion)	Revision Date: 2023/09/30	SDS Number: 5297463-00010	Date of last issue: 2023/04/04 Date of first issue: 2019/11/13
			r: NOAEL: 15 mg/kg body weight aplantation loss.
		Application Ro General Toxic Teratogenicity	nbryo-foetal development bute: Oral ity Maternal: NOAEL: 15 mg/kg body weight r: NOAEL: 15 mg/kg body weight nal toxicity observed.
Repro sessn	oductive toxicity - As- nent		e of adverse effects on sexual function and on development, based on animal experiment
Citric	acid:		
Effect ment	ts on foetal develop-	Species: Rat	e-generation reproduction toxicity study oute: Ingestion ve
II STOT	- single exposure		
	lassified based on avai	lable information.	
Com	oonents:		
Tulat	hromycin:		
	ssment		e or mixture is not classified as specific target , single exposure.
Hydro	ochloric acid:		
Asses	ssment	: May cause res	spiratory irritation.
Citric	acid:		
Asses	ssment	: May cause res	spiratory irritation.
STOT	- repeated exposure		
			prolonged or repeated exposure if swallowed.
Com	oonents:		
	hromycin:		
Expos	sure routes	: Oral	
	et Organs ssment		duce significant health effects in animals at cor 10 mg/kg bw or less.
_	ated dose toxicity		
Repe			
-	oonents:		



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I	Specie	S	:	Rat, male	
	NOAEI		:	>= 1,700 mg/kg	
		ation Route	÷	Ingestion	
	Exposi	ure time		2 yr	
	Tulath	romycin:			
	Specie		:	Rat	
	NOAEI		:	5 mg/kg	
	Applica	ation Route	:	Oral 3 Months	
	Exposit	ure time Organs	:	Liver	
	Sympto		:	Liver disorders	
I	Specie	<i>د</i>		Dog	
	NOAEL		÷	5 mg/kg	
		ation Route	:	Oral	
		ure time	:	3 Months	
		Organs	:	Liver, Eye	
l	Sympto	oms	:	Liver disorders, E	ye disease
	Citric a	acid:			
	Specie	s	:	Rat	
	NOAEI		:	4,000 mg/kg	
	LOAEL		:	8,000 mg/kg	
		ation Route ure time	÷	Ingestion 10 Days	
Į	Lypost		·	TO Days	
	Aspira	tion toxicity			
		ssified based on availa			
	Experi	ence with human exp	osu	ire	
	Compo	onents:			
	Tulath	romycin:			
	Ingesti	on	:	Symptoms: Diarrh	noea, Nausea, Abdominal pain, Vomiting
12 6		GICAL INFORMATION	J		
12.1	-0010				
	Ecoto	cicity			
	Compo	onents:			
	Propyl	ene glycol:			
	Toxicity	y to fish	:		hus mykiss (rainbow trout)): 40,613 mg/l
				Exposure time: 96	δh
	Tavisit	to double and attern			
		y to daphnia and other c invertebrates	:	EC50 (Ceriodaph Exposure time: 48	nia dubia (water flea)): 18,340 mg/l
	aquall				
	•				

SAFETY DATA SHEET



/ersion 7.0	Revision Date: 2023/09/30		OS Number: 97463-00010	Date of last issue: 2023/04/04 Date of first issue: 2019/11/13
Toxic plants	ity to algae/aquatic s	:	Exposure time:	nema costatum (marine diatom)): 19,300 mg/ 72 h Test Guideline 201
	ity to daphnia and other tic invertebrates (Chron- icity)	:	NOEC (Cerioda Exposure time:	aphnia dubia (water flea)): 13,020 mg/l 7 d
	ity to microorganisms	:	NOEC (Pseudo Exposure time:	monas putida): > 20,000 mg/l 18 h
Tulat	hromycin:			
	ity to fish	:	Exposure time:	ales promelas (fathead minnow)): 4 mg/l 96 h Test Guideline 203
	ity to daphnia and other tic invertebrates	:	Exposure time:	magna (Water flea)): > 100 mg/l 48 h Test Guideline 202
Toxic plants	ity to algae/aquatic s	:	mg/l End point: Grov Exposure time:	
			mg/l End point: Grov Exposure time:	
			End point: Grov Exposure time:	
			End point: Grov Exposure time:	
			0.0028 mg/l End point: Grov Exposure time:	
			0.0012 mg/l End point: Grov Exposure time:	

SAFETY DATA SHEET



M-Factor (Acute aquatic tox- icity) 100 M-Factor (Chronic aquatic 100 toxicity) Toxicity to microorganisms EC50: 41.1 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 EC10: 0.667 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 Citric acid: Toxicity to fish E LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 36 h Toxicity to dish : LC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h 3-Mercaptopropane-1,2-diol: : Ecotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability : Somponents: Propylene glycol: Biodegradability : Biodegradability : Result: Readily biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301B	Version 7.0	Revision Date: 2023/09/30	-	97463-00010	Date of last issue: 2023/04/04 Date of first issue: 2019/11/13
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Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d	Tula	thromycin:			
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Biodegradation: 97 % Exposure time: 28 d	Citri	c acid:			
	Biode	egradability	:	Biodegradation: 9 Exposure time: 28	97 % 3 d



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II				
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Partit	ylene glycol: ion coefficient: n- nol/water	:	log Pow: -1.07 Method: Regula	ion (EC) No. 440/2008, Annex, A.8
Partit	t hromycin: ion coefficient: n- nol/water	:	log Pow: -1.41 pH: 7	
Partit	c acid: ion coefficient: n- iol/water	:	log Pow: -1.72	
Partit	rcaptopropane-1,2-dic ion coefficient: n- ol/water	bl: :	log Pow: -0.84	
	lity in soil ata available			
	rdous to the ozone lay	yer		
	r adverse effects ata available			
13. DISPO	SAL CONSIDERATIO	NS		
Wast	osal methods e from residues aminated packaging	:	Do not dispose of Empty container dling site for rec	cordance with local regulations. of waste into sewer. s should be taken to an approved waste han- /cling or disposal. specified: Dispose of as unused product.
14. TRAN	SPORT INFORMATION	N		
Inter	national Regulations			
	TDG umber er shipping name	:	UN 3082 ENVIRONMENT N.O.S.	ALLY HAZARDOUS SUBSTANCE, LIQUID,

(Tulathromycin) 9

: : :

III

9

Class

Labels

Packing group





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Envii	onmentally hazardous	:	yes	
UN/I	-DGR D No. er shipping name	:	UN 3082 Environmentally h (Tulathromycin)	azardous substance, liquid, n.o.s.
Labe	ing group ls ing instruction (cargo	:	9 III Miscellaneous 964	
ger a	ing instruction (passen- ircraft) ronmentally hazardous	:	964 yes	
UN r	G-Code humber er shipping name	:	UN 3082 ENVIRONMENTA N.O.S. (Tulathromycin)	ALLY HAZARDOUS SUBSTANCE, LIQUID,
Labe EmS	ing group	:	9 III 9 F-A, S-F yes	

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance	
Chemical name	Number
Propane-1,2-diol	106



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Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Chemical name	Concentration (%)	Remarks
propane-1,2-diol	>=50 - <60	From April 1st, 2025
Hydrogen chloride	>=1 - <10	-
Sodium hydroxide	>=1 - <10	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
propane-1,2-diol	From April 1st, 2025
Hydrogen chloride	-
Sodium hydroxide	-

Ordinance on Prevention of Hazards Due to Specified Chemical Substances - Group 3 Substance

Chemical name	
hydrogen chloride	

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable



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Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission) Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

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

16. OTHER INFORMATION

Further information

Sources of key data used to :	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format

yyyy/mm/dd

:



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Full text of other abbreviations

ACGIH JP OEL JSOH	USA. ACGIH Threshold Limit Values (TLV) Japan. The Japan Society for Occupational Health. Recom- mendation of Occupational Exposure Limits
ACGIH / C JP OEL JSOH / OEL-C	Ceiling limit Occupational Exposure Limit-Ceiling

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 - 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.

JP / EN