

according to the Hazardous Products Regulations

Tulathromycin Formulation

Version 4.0	Revision Date: 07/06/2024		DS Number: 97455-00013	Date of last issue: 05/16/2024 Date of first issue: 11/13/2019	
SECTIC	N 1. IDENTIFICATION				
Product name Other means of identification			Tulathromycin Formulation AROVYN INJECTABLE SOLUTION (90779)		
Ма	nufacturer or supplier's	deta	ails		
Company name of supplier Address			Merck & Co., Inc 126 E. Lincoln Av Rahway, New Jer	enue sey U.S.A. 07065	
Telephone Emergency telephone E-mail address		:	908-740-4000 1-908-423-6000 EHSDATASTEWARD@merck.com		
Re	commended use of the c	hen	nical and restriction	ons on use	
Recommended use Restrictions on use		:	Veterinary productNot applicable		

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations Skin irritation : Category 2						
Serious eye damage	:	Category 1				
Skin sensitization	:	Category 1				
Reproductive toxicity	:	Category 2				
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Liver, Eye)				
GHS label elements Hazard pictograms	:					
Signal Word	:	Danger				
Hazard Statements	:	 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 prolonged or repeated exposure if swallowed. 				
Precautionary Statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read				

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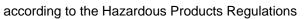
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rsion)	Revision Date: 07/06/2024	SDS Number: 5297455-00013	Date of last issue: 05/16/2024 Date of first issue: 11/13/2019
		P264 Wash ski P270 Do not ea P272 Contamir the workplace.	eathe mist or vapors. n thoroughly after handling. at, drink or smoke when using this product. nated work clothing should not be allowed out o tective gloves, protective clothing, eye protectio
		Response:	
		P302 + P352 IF P305 + P351 + water for sever and easy to do. CENTER. P308 + P313 IF P333 + P313 If tion.	 ON SKIN: Wash with plenty of water. P338 + P310 IF IN EYES: Rinse cautiously wi al minutes. Remove contact lenses, if present Continue rinsing. Immediately call a POISON exposed or concerned: Get medical attention skin irritation or rash occurs: Get medical atter ake off contaminated clothing and wash it before
		Storage:	
		P405 Store loc	ked up.
		Disposal:	
		P501 Dispose o disposal plant.	of contents and container to an approved waste
Other	· hazards		
••	known.		

Substance / Mixture : Mixture

		-	
Components			
Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Propylene glycol	1,2-Propanediol	57-55-6	50
Tulathromycin	No data availa- ble	217500-96-4	10
Hydrochloric acid	No data availa- ble	7647-01-0	<= 3
Citric acid	2- hydroxypro- pane-1,2,3- tricarboxylic acid	77-92-9	2
Sodium hydroxide	Caustic soda	1310-73-2	<= 1
3-Mercaptopropane- 1,2-diol	Thioglycerol	96-27-5	0.5

SECTION 4. FIRST AID MEASURES





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General advice		advice immed	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 in	haled	: If inhaled, rem Get medical a	nove to fresh air. ttention.		
In c	ase of skin contact	 In case of contact, immediately flush skin with plenty of v for at least 15 minutes while removing contaminated clot and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 			
In case of eye contact		: In case of con for at least 15 If easy to do,	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.		
lf s	wallowed	: If swallowed, Get medical a	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.		
and	st important symptoms I effects, both acute and ayed	: Causes skin in May cause an Causes seriou Suspected of Causes dama	 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 exposure if swallowed. 		
Pro	tection of first-aiders	: First Aid respo and use the re	onders should pay attention to self-protection, ecommended personal protective equipment ential for exposure exists (see section 8).		
Not	es to physician		natically 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.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Chlorine compounds Metal oxides
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES



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Personal precautions, protec- tive equipment and emer- gency procedures		:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective 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		:	For large spills, pr containment to kee can be pumped, s container. Clean up remainin absorbent. Local or national r disposal of this ma employed in the cl determine which r Sections 13 and 1	absorbent material. ovide diking or other appropriate ep material from spreading. If diked material tore recovered material in appropriate ag materials from spill with suitable egulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to egulations are applicable. 5 of this SDS provide information regarding tional requirements.	

SECTION 7. HANDLING AND STORAGE

Technical measures		See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation		Use only with adequate ventilation.
Advice on safe handling		Do not get on skin or clothing.
Advice on cale handling	•	Do not breathe mist or vapors.
		Do not swallow.
		Do not get in eyes.
		Wash skin thoroughly after handling.
		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure assessment
		Keep container tightly closed.
		Do not eat, drink or smoke when using this product.
		Take care to prevent spills, waste and minimize release to the
		environment.
Conditions for safe storage	:	Keep in properly labeled containers.
		Store locked up.
		Keep tightly closed.
		Store in accordance with the particular national regulations.
Materials to avoid		Do not store with the following product types:
	•	Strong oxidizing agents
		Self-reactive substances and mixtures
		Organic peroxides
		Explosives



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Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Propylene glycol	57-55-6	TWA (Va- pour and aerosols)	50 ppm 155 mg/m³	CA ON OEL
		TWA (aero- sol)	10 mg/m³	CA ON OEL
Tulathromycin	217500-96-4	TWA	300 µg/m3 (OEB 2)	Internal
	Further inform	Further information: DSEN		
		Wipe limit	100 µg/100 cm2	Internal
Hydrochloric acid	7647-01-0	(c)	2 ppm 3 mg/m ³	CA AB OEL
		С	2 ppm	CA BC OEL
		С	2 ppm	CA QC OEL
		С	2 ppm	ACGIH
Sodium hydroxide	1310-73-2	(c)	2 mg/m ³	CA AB OEL
		С	2 mg/m ³	CA BC OEL
		С	2 mg/m ³	CA QC OEL
		С	2 mg/m ³	ACGIH

Engineering measures	:	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 potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.
Personal protective equipme	ent	
Respiratory protection Filter type	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Combined particulates and acidic gas/vapor type
Hand protection		
Material	:	Chemical-resistant gloves
Remarks Eye protection	:	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



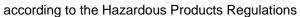
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Skin and body protection Hygiene measures		aerosols. : Work uniform o Additional body task being perfo	ect contact to the face with dusts, mists, or r laboratory coat. garments should be used based upon the prmed (e.g., sleevelets, apron, gauntlets, s) to avoid exposed skin surfaces.
		 Use appropriate degowning techniques to remove poter contaminated clothing. If exposure to chemical is likely during typical use, proviey flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the statement of the statement of the should not be allowed out of the statement of the statement	
		The effective op engineering cor appropriate deg	ated clothing before re-use. beration of a facility should include review of htrols, proper personal protective equipment, yowning and decontamination procedures, he monitoring, medical surveillance and the rative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	Colorless to pale yellow
Odor	:	slight
Odor Threshold	:	No data available
рН	:	5.1 - 5.7
Melting point/freezing point	:	190 - 192 °C
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available





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Rela	tive vapor density	:	No data available	
Rela	tive density	:	No data available)
Den	sity	:	1.07 g/cm ³	
	bility(ies) Vater solubility	:	> 1,000 mg/l	
	ition coefficient: n-	:	log Pow: -1.41	
	nol/water ignition temperature	:	No data available	9
Dec	omposition temperature	:	No data available	9
	osity ′iscosity, kinematic	:	No data available)
Expl	osive properties	:	Not explosive	
Oxid	lizing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	ecular weight	:	806.09 g/mol	
	icle characteristics icle size	:	Not applicable	

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

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

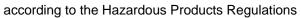
Acute toxicity

Not classified based on available information.

Product:

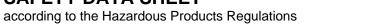
Acute oral toxicity

: Acute toxicity estimate: > 2,000 mg/kg



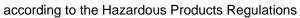


ersion D	Revision Date: 07/06/2024	SDS Numbe 5297455-00	
		Method:	Calculation method
Acute	e dermal toxicity		xicity estimate: > 2,000 mg/kg Calculation method
Com	oonents:		
Prop	ylene glycol:		
Acute	oral toxicity	: LD50 (R	at): 22,000 mg/kg
Acute	inhalation toxicity	Exposur	at): > 44.9 mg/l e time: 4 h nosphere: dust/mist
Acute	e dermal toxicity		abbit): > 2,000 mg/kg nent: The substance or mixture has no acute dermal
Tulat	hromycin:		
	oral toxicity		og): > 1,000 mg/kg Drgans: Gastrointestinal tract
			at): > 2,000 mg/kg Drgans: Gastrointestinal tract
Acute	e dermal toxicity		abbit): > 2,000 mg/kg Drgans: Gastrointestinal tract
II Hvdro	ochloric acid:		
	inhalation toxicity	Exposu	at): 8.3 mg/l e time: 30 min nosphere: dust/mist
Citric	acid:		
	e oral toxicity	: LD50 (N	louse): 5,400 mg/kg
Acute	e dermal toxicity	Method:	at): > 2,000 mg/kg OECD Test Guideline 402 nent: The substance or mixture has no acute dermal
II Sodiu	um hydroxide:		
	inhalation toxicity	: Assessr	nent: Corrosive to the respiratory tract.
3-Mei	rcaptopropane-1,2-d	iol:	
	oral toxicity		at): 648 mg/kg
Aquito	e dermal toxicity	: LD50 (R	abbit): 673 mg/kg





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	orrosion/irritation			
Cause	s skin irritation.			
<u>Comp</u>	onents:			
Propy	lene glycol:			
Specie		:	Rabbit	
Metho		:	OECD Test Guid	leline 404
Result		:	No skin irritation	
Tulath	romycin:			
Specie		:	Rabbit	
Result		:	No skin irritation	
Hydro	chloric acid:			
Specie		:		man epidermis (RhE)
Metho	d	:	OECD Test Guid	leline 431
Result		:	Corrosive after 3	minutes or less of exposure
Citric	acid:			
Specie	es	:	Rabbit	
Metho		:	OECD Test Guid	leline 404
Result		:	No skin irritation	
Sodiu	m hydroxide:			
Result		:	Corrosive after 3	minutes or less of exposure
3-Mer	captopropane-1,2-di	iol:		
Specie	es	:	Rabbit	
Result		:	Skin irritation	
Seriou	ıs eye damage/eye i	rritati	on	
Cause	s serious eye damag	e.		
<u>Comp</u>	onents:			
Propy	lene glycol:			
Specie	es	:	Rabbit	
Result		:	No eye irritation	
Metho	d	:	OECD Test Guid	leline 405
Tulath	romycin:			
Specie		:	Rabbit	
Result		:	Irreversible effec	ts on the eye
Hydro	chloric acid:			
Specie	es	:	Bovine cornea	



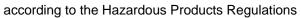


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Metho	od	:	OECD Test Guide	eline 437
Result	t	:	Irreversible effect	ts on the eye
Citric	acid:			
Specie		:	Rabbit	
Result Metho		÷	OECD Test Guide	reversing within 21 days
Metho		•		
Sodiu	ım hydroxide:			
Result		:	Irreversible effect	
Rema	rks	:	Based on skin co	rrosivity.
3-Mer	captopropane-1,2-dio	I:		
Specie		:	Rabbit	
Result		:	Irritation to eyes,	reversing within 21 days
Respi	ratory or skin sensitiz	atic	on	
Skin s	sensitization			
May c	ause an allergic skin re	actio	on.	
Respi	ratory sensitization			
Not cla	assified based on availa	able	information.	
Comp	onents:			
Propy	lene glycol:			
Test T	•••	:	Maximization Tes	st
	s of exposure	:	Skin contact	
Specie Result		÷	Guinea pig negative	
i vesui	L	•	negative	
Tulath	nromycin:			
Test T	-	:	Maximization Tes	st
	s of exposure	:	Skin contact	
Specie	es sment	÷	Guinea pig	tization by skin contact.
Result		÷	Causes sensitiza	
	ochloric acid:			
Test T	⁻ype s of exposure	÷	Maximization Tes Skin contact	st
Specie	es	÷	Guinea pig	
Metho	od	:	OECD Test Guid	eline 406
Result	t	:	negative	
ومطانب	m hydroxido.			
Test T	m hydroxide:		Human repeating	sult patch test (HRIPT)
	λhe	·	numan repeat ins	$\sum_{i=1}^{n} \sum_{j=1}^{n} \sum_{i=1}^{n} \sum_{i=1}^{n} \sum_{i=1}^{n} \sum_{j=1}^{n} \sum_{i$



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Route Resu	es of exposure It	: Skin contact : negative	
3-Mei	rcaptopropane-1,2-d	iol:	
Test Route Speci Metho Resu	es of exposure les od	E Local lymph r Skin contact Mouse OECD Test G positive	node assay (LLNA) Guideline 429
Asses	ssment	: Probability or rate in human	evidence of low to moderate skin sensitization
	cell mutagenicity lassified based on ava	ilable information.	
Com	oonents:		
	ylene glycol: toxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
			nromosome aberration test in vitro D Test Guideline 473 ive
Geno	toxicity in vivo	cytogenetic a Species: Mou	se oute: Intraperitoneal injection
Tulat	hromycin:		
	toxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive
		Test Type: Cł Result: negat	nromosome aberration test in vitro ive
Geno	toxicity in vivo	: Test Type: Ma cytogenetic a Species: Rat Result: negat	••
	cell mutagenicity -	: Weight of evid cell mutagen.	dence does not support classification as a germ
Hydro	ochloric acid:		
	toxicity in vitro	: Test Type: Sa assay (in vitro Result: negat	





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П			
	c acid:		
Geno	otoxicity in vitro	: Test Type: Bacterial reverse mutation assay (Result: negative	AMES)
		Test Type: in vitro micronucleus test Result: positive	
		Test Type: Bacterial reverse mutation assay (<i>,</i> Result: negative	AMES)
Genc	otoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian b cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative	one-marrow
3-Me	rcaptopropane-1,2-di		
Geno	otoxicity in vitro	: Test Type: Bacterial reverse mutation assay (Method: OECD Test Guideline 471 Result: negative	AMES)
		Remarks: Based on data from similar material	S
		Test Type: In vitro mammalian cell gene muta Method: OECD Test Guideline 476 Result: negative	tion test
		Remarks: Based on data from similar material	S
		Test Type: Chromosome aberration test in vitr Method: OECD Test Guideline 473 Result: negative	0
		Remarks: Based on data from similar material	S
II Carc	inogenicity		
	lassified based on ava	ble information.	
<u>Com</u>	ponents:		
Prop	ylene glycol:		
Spec		: Rat	
	cation Route sure time	: Ingestion : 2 Years	
Resu		: negative	
Tulat	thromycin:		
Carci ment	inogenicity - Assess-	: No data available	
Hydr	ochloric acid:		
Spec		: Rat	
	cation Route sure time	: Inhalation : 128 weeks	

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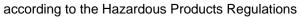
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Resul	t	:	negative	
Suspe	oductive toxicity ected of damaging fertilit conents:	ty or	the unborn child.	
Propy	/lene glycol:			
	s on fertility	:	Test Type: Two-g Species: Mouse Application Route Result: negative	eneration reproduction toxicity study : Ingestion
Effect	s on fetal development	:	Test Type: Embry Species: Mouse Application Route Result: negative	o-fetal development : Ingestion
Tulati	hromycin:			
	s on fertility	:	Species: Rat Application Route Fertility: NOAEL:	y/early embryonic development : Oral 100 mg/kg body weight cant adverse effects were reported
Effect	s on fetal development	:	Species: Rat Application Route General Toxicity N	Maternal: NOAEL: 15 mg/kg body weight DAEL: 15 mg/kg body weight
			Application Route General Toxicity	Maternal: NOAEL: 15 mg/kg body weight DAEL: 15 mg/kg body weight
Repro sessm	oductive toxicity - As- nent	:		f adverse effects on sexual function and development, based on animal experiments.
Citric	acid:			
Effect	s on fetal development	:	Test Type: One-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion
3-Mer	captopropane-1,2-diol	:		
	s on fertility	:	Test Type: Two-g Species: Rat Application Route	eneration reproduction toxicity study : Ingestion



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			Result: negative	Test Guideline 416 I on data from similar materials
Effect	ts on fetal development	:	Species: Rat Application Rout Method: OECD Result: negative	Test Guideline 414
	-single exposure lassified based on availa	able	information.	
<u>Com</u>	oonents:			
Tulat	hromycin:			
	ssment	:	The substance o organ toxicant, s	r mixture is not classified as specific target ingle exposure.
	ochloric acid:			
Asses	ssment	:	May cause respi	ratory irritation.
Citric	acid:			
Citric Asses		:	May cause respi	ratory irritation.
Asses STOT Cause <u>Comp</u> Tulat Route Targe	ssment	: iver	Eye) through pro Oral Liver, Eye Shown to produc	ratory irritation. longed or repeated exposure if swallowed. ce significant health effects in animals at con- mg/kg bw or less.
Asses STOT Cause Comu Tulat Route Targe Asses	ssment F-repeated exposure es damage to organs (L <u>ponents:</u> hromycin: es of exposure et Organs	: iver : :	Eye) through pro Oral Liver, Eye Shown to produc	longed or repeated exposure if swallowed.
Asses STOT Cause Comu Tulat Route Targe Asses Repe	F-repeated exposure es damage to organs (L <u>ponents:</u> hromycin: es of exposure et Organs ssment	: iver : :	Eye) through pro Oral Liver, Eye Shown to produc	longed or repeated exposure if swallowed.
Asses STOT Cause Com Tulat Route Asses Repe <u>Com</u>	Sement F-repeated exposure es damage to organs (L <u>ponents:</u> hromycin: es of exposure et Organs ssment ated dose toxicity	: iver : :	Eye) through pro Oral Liver, Eye Shown to produc	longed or repeated exposure if swallowed.
Asses STOT Cause Com Tulat Route Targe Asses Repe <u>Com</u> Speci	Sement F-repeated exposure es damage to organs (L ponents: hromycin: es of exposure et Organs sement ated dose toxicity ponents: ylene glycol: les	iver	Eye) through pro Oral Liver, Eye Shown to produc centrations of 10	longed or repeated exposure if swallowed.
Asses STOT Cause Comp Tulat Route Targe Asses Repe <u>Comp</u> Speci NOAE	Sement F-repeated exposure es damage to organs (L ponents: hromycin: es of exposure et Organs ssment ated dose toxicity ponents: ylene glycol: les EL	iver	Eye) through pro Oral Liver, Eye Shown to produc centrations of 10 Rat, male >= 1,700 mg/kg	longed or repeated exposure if swallowed.
Asses STOT Cause Comp Tulat Route Targe Asses Repe <u>Comp</u> Speci NOAE Applic	Sement F-repeated exposure es damage to organs (L ponents: hromycin: es of exposure et Organs sement ated dose toxicity ponents: ylene glycol: les	: iver. : : :	Eye) through pro Oral Liver, Eye Shown to produc centrations of 10	longed or repeated exposure if swallowed.
Asses STOT Cause Comp Tulat Route Targe Asses Repe <u>Comp</u> Prop Speci NOAE Applic Expos	Sement F-repeated exposure es damage to organs (L ponents: hromycin: es of exposure et Organs sement ated dose toxicity ponents: ylene glycol: les EL cation Route sure time	: iver. : : :	Eye) through pro Oral Liver, Eye Shown to produc centrations of 10 Rat, male >= 1,700 mg/kg Ingestion	longed or repeated exposure if swallowed.
Asses STOT Cause Comp Tulat Route Targe Asses Repe <u>Comp</u> Prop Speci NOAE Applic Expos	Sement F-repeated exposure es damage to organs (L ponents: hromycin: es of exposure et Organs sement ated dose toxicity ponents: ylene glycol: les EL cation Route sure time hromycin:	: iver. : : :	Eye) through pro Oral Liver, Eye Shown to produc centrations of 10 Rat, male >= 1,700 mg/kg Ingestion	longed or repeated exposure if swallowed.



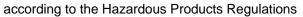


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Expos	cation Route sure time et Organs etoms	:	Oral 3 Months Liver Liver disorders	
Expos	EL cation Route sure time et Organs		Dog 5 mg/kg Oral 3 Months Liver, Eye Liver disorders, E	ye disease
Speci NOAE LOAE Applic	EL	:	Rat 4,000 mg/kg 8,000 mg/kg Ingestion 10 Days	
Speci LOAE Applio	EL cation Route sure time od	:	Rat > 100 mg/kg Ingestion 55 Days OECD Test Guide Based on data fro	eline 422 m similar materials
Not cl Expe	ration toxicity lassified based on availa rience with human exp ponents:			
Tulat Inges	hromycin: tion	:	Symptoms: Diarrh	nea, Nausea, Abdominal pain, Vomiting
Ecoto	12. ECOLOGICAL INFO	DRI	I ATION	
	ylene glycol: ity to fish	:	LC50 (Oncorhync Exposure time: 96	hus mykiss (rainbow trout)): 40,613 mg/l ∂ h
	ity to daphnia and other ic invertebrates	:	EC50 (Ceriodaph Exposure time: 48	nia dubia (water flea)): 18,340 mg/l 3 h
Toxic	ity to algae/aquatic	:	ErC50 (Skeletone	ma costatum (marine diatom)): 19,300 mg/l



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plants			Exposure time: 72 Method: OECD Te	
	invertebrates (Chron-	:	NOEC (Ceriodaph Exposure time: 7	nnia dubia (water flea)): 13,020 mg/l d
	/ to microorganisms	:	NOEC (Pseudome Exposure time: 18	onas putida): > 20,000 mg/l 3 h
Tulath	romycin:			
Toxicity	•	:	LC50 (Pimephales Exposure time: 96 Method: OECD Te	
	/ to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
Toxicity plants	/ to algae/aquatic	:	EC50 (Pseudokiro mg/l End point: Growth Exposure time: 72 Method: OECD To	2 h
			EC10 (Pseudokiro mg/l End point: Growth Exposure time: 72 Method: OECD To	2 h
			EC50 (Anabaena End point: Growth Exposure time: 72 Method: OECD Te	2 h
			EC10 (Anabaena End point: Growth Exposure time: 72 Method: OECD To	2 h
			EC50 (Synechoco 0.0028 mg/l End point: Growth Exposure time: 72 Method: OECD To	2 h
			EC10 (Synechoco 0.0012 mg/l End point: Growth Exposure time: 72 Method: OECD Te	2 h
Toxicity	/ to microorganisms	:	EC50: 41.1 mg/l	





Tulathromycin Formulation

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			Exposure time: 3 Test Type: Respir Method: OECD T	ation inhibition of activated sludge
			EC10: 0.667 mg/l Exposure time: 3 Test Type: Respir Method: OECD To	ation inhibition of activated sludge
Citric	acid:			
	ity to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): > 100 mg/l 5 h
	ity to daphnia and other tic invertebrates	:	EC50 (Daphnia m Exposure time: 24	agna (Water flea)): 1,535 mg/l I h
11 3-Mo	rcaptopropane-1,2-diol			
	ity to fish	:	Exposure time: 96 Method: OECD T	
	ity to daphnia and other tic invertebrates	:	Exposure time: 48 Method: OECD T	
Toxic plants	ity to algae/aquatic s	:	10 - 100 mg/l Exposure time: 72 Method: OECD T	
			mg/l Exposure time: 72 Method: OECD T	
Toxic	ity to microorganisms	:	Exposure time: 3 Method: OECD T	h
Persi	stence and degradabili	ity		
	ponents:	•		
Prop	ylene glycol: egradability	:	Result: Readily bi Biodegradation: 9	98.3 %

Exposure time: 28 d



according to the Hazardous Products Regulations

ersion 0	Revision Date: 07/06/2024		OS Number: 97455-00013	Date of last issue: 05/16/2024 Date of first issue: 11/13/2019
			Method: OECD	Test Guideline 301F
	hromycin:		Regult: Not room	like biodogradabla
Biodegradability		·	Exposure time:	dily biodegradable. 29 d Test Guideline 301B
Citric	c acid:			
Biode	egradability	:	Result: Readily Biodegradation: Exposure time: Method: OECD	97 %
3-Me	rcaptopropane-1,2-di	iol:		
Biode	egradability	:	Result: Readily Remarks: Base	biodegradable. d on data from similar materials
Bioa	ccumulative potentia	I		
<u>Com</u>	ponents:			
Prop	ylene glycol:			
	ion coefficient: n- ol/water	:	log Pow: -1.07 Method: Regula	tion (EC) No. 440/2008, Annex, A.8
Tulat	hromycin:			
	ion coefficient: n- nol/water	:	log Pow: -1.41 pH: 7	
Citric	c acid:			
Partit	ion coefficient: n- nol/water	:	log Pow: -1.72	
3-Me	rcaptopropane-1,2-di	iol:		
	ion coefficient: n- ool/water	:	log Pow: -0.84 Method: OECD	Test Guideline 117
Mobi	lity in soil			
	ata available			
Othe	r adverse effects			
No da	ata available			

Disposal methods		
Waste 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 approved waste

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				r recycling or disposal. specified: Dispose of as unused product.
SECTION	I 14. TRANSPORT INFO	ORM	ATION	
Inter	national Regulations			
UNR	TDG			
UN n	number	:	UN 3082	
Prop	er shipping name	:	ENVIRONMEN N.O.S. (Tulathromycin	TALLY HAZARDOUS SUBSTANCE, LIQUID,)
Class		:	9	
	ing group	:		
Labe	onmentally hazardous	÷	9	
	-	•	yes	
	A -DGR D No.			
	er shipping name	:	UN 3082 Environmentally	/ hazardous substance, liquid, n.o.s.
тюр		•	(Tulathromycin	
Class	S	:	9	,
	ing group	:	111	
Labe		:	Miscellaneous	
Pack	ting instruction (cargo	•	964	
	ing instruction (passen-	:	964	
	aircraft)	•	001	
Ĕnvir	ronmentally hazardous	:	yes	
IMDO	G-Code			
	number	:	UN 3082	
Prop	er shipping name	:		TALLY HAZARDOUS SUBSTANCE, LIQUID,
			N.O.S.	
Class	e		(Tulathromycin) 9	
	ing group	÷		
Labe		:	9	
	Code	:	F-A, S-F	
Marin	ne pollutant	:	yes	
Tran	sport in bulk according	g to	Annex II of MAF	RPOL 73/78 and the IBC Code
Not a	applicable for product as	sup	plied.	
Dom	estic regulation			
TDG				
	number	:	UN 3082	
Prop	er shipping name	:	ENVIRONMEN N.O.S. (Tulathromycin	TALLY HAZARDOUS SUBSTANCE, LIQUID,
Class	S	:	9	/
			in .	

SDS Number:

: yes(Tulathromycin)

: 111

: 9

: 171

Packing group

Marine pollutant

ERG Code

Labels



according to the Hazardous Products Regulations

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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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations	5
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ACGIH CA AB OEL		USA. ACGIH Threshold Limit Values (TLV) Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA ON OEL	:	Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
CA QC OEL	:	Québec. Regulation respecting occupational health and safe- ty, Schedule 1, Part 1: Permissible exposure values for air- borne contaminants
ACGIH / C	:	Ceiling limit
CA AB OEL / (c)	:	ceiling occupational exposure limit
CA BC OEL / C	:	ceiling limit
CA ON OEL / TWA	:	Time-Weighted Average Limit (TWA)
CA QC OEL / C	:	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



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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

Sources of key data used to compile the Material 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/
Revision Date Date format	-	07/06/2024 mm/dd/yyyy

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

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.

CA / Z8