

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Tulathromycin Formulation

Other means of identification : AROVYN INJECTABLE SOLUTION (90779)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)


Skin irritation, Category 2	H315: Causes skin irritation.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 2	H361: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Tulathromycin Formulation

Version 9.0 Revision Date: 14.04.2025 SDS Number: 5297469-00015 Date of last issue: 04.12.2024
 Date of first issue: 13.11.2019

- 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 through prolonged or repeated exposure.
 H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements :
Prevention:
 P201 Obtain special instructions before use.
 P264 Wash skin thoroughly after handling.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
 P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
 P391 Collect spillage.

Hazardous components which must be listed on the label:

Tulathromycin
 Hydrochloric acid
 Sodium hydroxide
 3-Mercaptopropane-1,2-diol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Tulathromycin	217500-96-4	Eye Dam. 1; H318 Skin Sens. 1; H317 Repr. 2; H361 STOT RE 1; H372	>= 10 - < 20

Tulathromycin Formulation

Version 9.0 Revision Date: 14.04.2025 SDS Number: 5297469-00015 Date of last issue: 04.12.2024
 Date of first issue: 13.11.2019

		(Liver, Eye) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100	
Hydrochloric acid	7647-01-0 231-595-7 017-002-01-X 01-2119484862-27	Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318	$\geq 3 - < 5$
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	$\geq 1 - < 10$
Sodium hydroxide	1310-73-2 215-185-5 011-002-00-6	Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318	$\geq 1 - < 2$
3-Mercaptopropane-1,2-diol	96-27-5 202-495-0	Acute Tox. 4; H302 Acute Tox. 3; H311 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1B; H317	$\geq 0,1 - < 1$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
 When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- 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.

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

- Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : 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.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : 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.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

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

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Chlorine compounds
Metal oxides

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.
Do not breathe mist or vapours.
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.

Tulathromycin Formulation

Version 9.0 Revision Date: 14.04.2025 SDS Number: 5297469-00015 Date of last issue: 04.12.2024
 Date of first issue: 13.11.2019

Do not eat, drink or smoke when using this product.
 Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye 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 workplace. Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
 Strong oxidizing agents
 Self-reactive substances and mixtures
 Organic peroxides
 Explosives
 Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	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- RL STEL/C (Gas and aerosol mists)	4 ppm	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			
		TWA	5 ppm 8 mg/m3	2000/39/EC
		STEL	10 ppm 15 mg/m3	2000/39/EC
Sodium hydroxide	1310-73-2	OEL- RL STEL/C	4 mg/m3	ZA OEL
	Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents			

Tulathromycin Formulation

Version 9.0 Revision Date: 14.04.2025 SDS Number: 5297469-00015 Date of last issue: 04.12.2024
 Date of first issue: 13.11.2019

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	50 mg/m ³
Hydrochloric acid	Workers	Inhalation	Long-term local effects	8 mg/m ³
	Workers	Inhalation	Acute local effects	15 mg/m ³
	Consumers	Inhalation	Long-term local effects	8 mg/m ³
	Consumers	Inhalation	Acute local effects	15 mg/m ³
Sodium hydroxide	Consumers	Inhalation	Long-term local effects	1 mg/m ³
	Workers	Inhalation	Long-term local effects	1 mg/m ³
	Workers	Ingestion	Long-term systemic effects	0,49 mg/m ³
	Workers	Skin contact	Long-term systemic effects	0,14 mg/kg bw/day
3-Mercaptopropane-1,2-diol	Consumers	Ingestion	Long-term systemic effects	0,074 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	0,05 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,05 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,05 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57,2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
Citric acid	Fresh water	0,44 mg/l
	Marine water	0,044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34,6 mg/kg dry weight (d.w.)
	Marine sediment	3,46 mg/kg dry weight (d.w.)
	Soil	33,1 mg/kg dry weight (d.w.)

Tulathromycin Formulation

Version 9.0 Revision Date: 14.04.2025 SDS Number: 5297469-00015 Date of last issue: 04.12.2024
 Date of first issue: 13.11.2019

		weight (d.w.)
3-Mercaptopropane-1,2-diol	Fresh water	0,006 mg/l
	Freshwater - intermittent	0,057 mg/l
	Marine water	0,001 mg/l

8.2 Exposure controls

Engineering measures

The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

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 equipment

- Eye/face protection : Wear safety glasses with side shields or goggles.
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Skin and body protection : Work uniform or laboratory coat.
 Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
 Use appropriate degowning techniques to remove potentially contaminated clothing.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Combined particulates and acidic gas/vapour type (E-P)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

- Appearance : liquid
- Colour : Colorless to pale yellow
- Odour : slight
- Odour Threshold : No data available

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

pH	:	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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1,07 g/cm ³
Solubility(ies)		
Water solubility	:	> 1.000 mg/l
Partition coefficient: n-octanol/water	:	log Pow: -1,41
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Molecular weight	:	806,09 g/mol
Particle size	:	Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

|| Not classified based on available information.

Product:

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

Tulathromycin:

|| Acute oral toxicity : LD50 (Dog): > 1.000 mg/kg
Target Organs: Gastrointestinal tract

LD50 (Rat): > 2.000 mg/kg
Target Organs: Gastrointestinal tract

|| Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Target Organs: Gastrointestinal tract

Hydrochloric acid:

|| Acute inhalation toxicity : LC50 (Rat, male): 8,3 mg/l
Exposure time: 30 min
Test atmosphere: dust/mist
Assessment: Corrosive to the respiratory tract.
Remarks: No test guideline followed

Citric acid:

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

Acute oral toxicity	: LD50 (Mouse): 5.400 mg/kg
Acute dermal toxicity	: LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

Sodium hydroxide:

Acute inhalation toxicity	: Assessment: Corrosive to the respiratory tract.
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3-Mercaptopropane-1,2-diol:

Acute oral toxicity	: LD50 (Rat): 648 mg/kg
Acute dermal toxicity	: LD50 (Rabbit): 673 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:**Tulathromycin:**

Species	: Rabbit
Result	: No skin irritation

Hydrochloric acid:

Species	: reconstructed human epidermis (RhE)
Method	: OECD Test Guideline 431
Remarks	: The test was conducted according to guideline
Result	: Corrosive after 3 minutes or less of exposure

Citric acid:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

Sodium hydroxide:

Result	: Corrosive after 3 minutes or less of exposure
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3-Mercaptopropane-1,2-diol:

Species	: Rabbit
Result	: Skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:**Tulathromycin:**

Species	: Rabbit
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Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

|| Result : Irreversible effects on the eye

Hydrochloric acid:

|| Species : Bovine cornea
|| Method : OECD Test Guideline 437
|| Remarks : The test was conducted according to guideline

|| Result : Irreversible effects on the eye

Citric acid:

|| Species : Rabbit
|| Method : OECD Test Guideline 405
|| Result : Irritation to eyes, reversing within 21 days

Sodium hydroxide:

|| Result : Irreversible effects on the eye
|| Remarks : Based on skin corrosivity.

3-Mercaptopropane-1,2-diol:

|| Species : Rabbit
|| Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation**Skin sensitisation**

|| May cause an allergic skin reaction.

Respiratory sensitisation

|| Not classified based on available information.

Components:**Tulathromycin:**

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

Hydrochloric acid:

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

Sodium hydroxide:

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

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

3-Mercaptopropane-1,2-diol:

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: positive
Assessment	: Probability or evidence of low to moderate skin sensitisation rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:**Tulathromycin:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Result: negative
Germ cell mutagenicity- Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

Hydrochloric acid:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: No test guideline followed
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Citric acid:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro micronucleus test Result: positive Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

3-Mercaptopropane-1,2-diol:

	Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES)	
			Method: OECD Test Guideline 471	
			Result: negative	
				Remarks: Based on data from similar materials
		:	Test Type: In vitro mammalian cell gene mutation test	
			Method: OECD Test Guideline 476	
			Result: negative	
				Remarks: Based on data from similar materials
		:	Test Type: Chromosome aberration test in vitro	
		Method: OECD Test Guideline 473		
		Result: negative		
			Remarks: Based on data from similar materials	

Carcinogenicity

|| Not classified based on available information.

Components:**Tulathromycin:**

	Carcinogenicity - Assessment	:	No data available
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Hydrochloric acid:

	Species	:	Rat, male
	Application Route	:	inhalation (gas)
	Exposure time	:	128 weeks
	Result	:	negative
	Remarks	:	No test guideline followed

Reproductive toxicity

|| Suspected of damaging fertility or the unborn child.

Components:**Tulathromycin:**

	Effects on fertility	:	Test Type: Fertility/early embryonic development
			Species: Rat
			Application Route: Oral
			Fertility: NOAEL: 100 mg/kg body weight
			Result: No significant adverse effects were reported
	Effects on foetal development	:	Test Type: Embryo-foetal development
			Species: Rat
			Application Route: Oral
			General Toxicity Maternal: NOAEL: 15 mg/kg body weight
			Teratogenicity: NOAEL: 15 mg/kg body weight
		Result: Postimplantation loss.	
			Test Type: Embryo-foetal development
			Application Route: Oral
			General Toxicity Maternal: NOAEL: 15 mg/kg body weight

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

Teratogenicity: NOAEL: 15 mg/kg body weight
Result: Maternal toxicity observed.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

Citric acid:

Effects on foetal development : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

3-Mercaptopropane-1,2-diol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

Components:**Tulathromycin:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Citric acid:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:**Tulathromycin:**

Exposure routes : Oral
Target Organs : Liver, Eye
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

Repeated dose toxicity**Components:****Tulathromycin:**

Species	: Rat
NOAEL	: 5 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Liver
Symptoms	: Liver disorders

Species	: Dog
NOAEL	: 5 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Liver, Eye
Symptoms	: Liver disorders, Eye disease

Hydrochloric acid:

Species	: Rat, male
LOAEL	: > 12,5 mg/kg
Application Route	: Ingestion
Exposure time	: 2 yr
Method	: OECD Test Guideline 453
Remarks	: The test was conducted equivalent or similar to guideline Based on data from similar materials

Citric acid:

Species	: Rat
NOAEL	: 4.000 mg/kg
LOAEL	: 8.000 mg/kg
Application Route	: Ingestion
Exposure time	: 10 Days

3-Mercaptopropane-1,2-diol:

Species	: Rat
LOAEL	: > 100 mg/kg
Application Route	: Ingestion
Exposure time	: 55 Days
Method	: OECD Test Guideline 422
Remarks	: Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Tulathromycin:**

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

|| Ingestion : Symptoms: Diarrhoea, Nausea, Abdominal pain, Vomiting

SECTION 12: Ecological information**12.1 Toxicity****Components:****Tulathromycin:**

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 4 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 0,044 mg/l End point: Growth Exposure time: 72 h Method: OECD Test Guideline 201
	EC10 (Pseudokirchneriella subcapitata (green algae)): 0,014 mg/l End point: Growth Exposure time: 72 h Method: OECD Test Guideline 201
	EC50 (Anabaena flos-aquae): 0,0023 mg/l End point: Growth Exposure time: 72 h Method: OECD Test Guideline 201
	EC10 (Anabaena flos-aquae): 0,00035 mg/l End point: Growth Exposure time: 72 h Method: OECD Test Guideline 201
	EC50 (Synechococcus leopoliensis (blue-green algae)): 0,0028 mg/l End point: Growth Exposure time: 72 h Method: OECD Test Guideline 201
	EC10 (Synechococcus leopoliensis (blue-green algae)): 0,0012 mg/l End point: Growth Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 100
Toxicity to microorganisms	: EC50 : 41,1 mg/l

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

	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
M-Factor (Chronic aquatic toxicity)	: 100
Hydrochloric acid:	
Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: The test was conducted according to guideline Based on data from similar materials
Toxicity to algae/aquatic plants	: ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: The test was conducted according to guideline Based on data from similar materials
	EC10 (Raphidocelis subcapitata (freshwater green alga)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: The test was conducted according to guideline Based on data from similar materials
Toxicity to microorganisms	: EC10 (activated sludge): > 1 mg/l Exposure time: 3 h Remarks: Based on data from similar materials
Toxicity to fish (Chronic toxicity)	: NOEC: > 1 mg/l Exposure time: 33 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210 Remarks: The test was conducted equivalent or similar to guideline Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: > 1 mg/l Exposure time: 21 d Species: Daphnia pulex (Water flea) Method: OECD Test Guideline 211 Remarks: The test was conducted equivalent or similar to guideline

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

Based on data from similar materials

Citric acid:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1.535 mg/l Exposure time: 24 h

3-Mercaptopropane-1,2-diol:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 10 - 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 10 - 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
		EC10 (Raphidocelis subcapitata (freshwater green alga)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC10 (activated sludge): > 1 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials

12.2 Persistence and degradability**Components:****Tulathromycin:**

Biodegradability	:	Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B
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Citric acid:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d Method: OECD Test Guideline 301B
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Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

3-Mercaptopropane-1,2-diol:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential**Components:****Tulathromycin:**

Partition coefficient: n-octanol/water : log Pow: -1,41
pH: 7

Citric acid:

Partition coefficient: n-octanol/water : log Pow: -1,72

3-Mercaptopropane-1,2-diol:

Partition coefficient: n-octanol/water : log Pow: -0,84
Method: OECD Test Guideline 117

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects**Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information**14.1 UN number**

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
IATA	:	UN 3082

14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tulathromycin)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tulathromycin)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tulathromycin)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tulathromycin)
IATA	:	Environmentally hazardous substance, liquid, n.o.s. (Tulathromycin)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
IATA	:	9

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

Tunnel restriction code : (-)

RID

Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9

IMDG

Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft)	: 964
Packing instruction (LQ)	: Y964
Packing group	: III
Labels	: Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft)	: 964
Packing instruction (LQ)	: Y964
Packing group	: III
Labels	: Miscellaneous

14.5 Environmental hazards**ADN**

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Full text of H-Statements

H290	:	May be corrosive to metals.
H302	:	Harmful if swallowed.
H311	:	Toxic in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H335	:	May cause respiratory irritation.
H361	:	Suspected of damaging fertility or the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Met. Corr.	:	Corrosive to metals
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
Skin Irrit.	:	Skin irritation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
2000/39/EC	:	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits

2000/39/EC / TWA : Limit Value - eight hours

2000/39/EC / STEL : Short term exposure limit

ZA OEL / OEL- RL STEL/C : Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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 Agency, <http://echa.europa.eu/>

Classification of the mixture:

Skin Irrit. 2	H315
Eye Dam. 1	H318
Skin Sens. 1	H317
Repr. 2	H361
STOT RE 1	H372
Aquatic Acute 1	H400

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	5297469-00015	Date of first issue: 13.11.2019

Aquatic Chronic 1

H410

Calculation method

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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.

ZA / EN