

# SAFETY DATA SHEET



## 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

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### 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 Substance/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

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### 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)

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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.

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## 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

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		(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	>= 3 - < 5
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 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	>= 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	>= 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.

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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.

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

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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

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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.

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Hygiene measures	<p>Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.</p> <p>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.</p> <p>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.</p>
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### 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/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
Hydrochloric acid	7647-01-0	Wipe limit OEL- RL STEL/C (Gas and aerosol mists)	100 µg/100 cm <sup>2</sup> 4 ppm	Internal ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
		TWA	5 ppm 8 mg/m <sup>3</sup>	2000/39/EC
		STEL	10 ppm 15 mg/m <sup>3</sup>	2000/39/EC
Sodium hydroxide	1310-73-2	OEL- RL STEL/C	4 mg/m <sup>3</sup>	ZA OEL
		Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents		

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### 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/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local effects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Hydrochloric acid	Workers	Inhalation	Long-term local effects	8 mg/m3
	Workers	Inhalation	Acute local effects	15 mg/m3
	Consumers	Inhalation	Long-term local effects	8 mg/m3
	Consumers	Inhalation	Acute local effects	15 mg/m3
Sodium hydroxide	Consumers	Inhalation	Long-term local effects	1 mg/m3
	Workers	Inhalation	Long-term local effects	1 mg/m3
3-Mercaptopropane-1,2-diol	Workers	Ingestion	Long-term systemic effects	0,49 mg/m3
	Workers	Skin contact	Long-term systemic effects	0,14 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,074 mg/m3
	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

### 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.)
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

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		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

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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/cm³
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

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

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**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.

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**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:**

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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.

### 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

### 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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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

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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

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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.
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**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.
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**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

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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.

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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:**

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||| 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

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		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
<b>Hydrochloric acid:</b>		
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

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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

#### **Citric acid:**

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

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**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.

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**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.

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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
<b>ADN</b>	: 9	
<b>ADR</b>	: 9	
<b>RID</b>	: 9	
<b>IMDG</b>	: 9	
<b>IATA</b>	: 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

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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.

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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.

**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

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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; AIIC - 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

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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