

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 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

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)

Hazard pictograms :



Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 Date of first issue: 13.11.2019

- 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 (Liver, Eye) Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 10 - < 20

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 Date of first issue: 13.11.2019

		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 STOT SE 3; H335	>= 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; H331 Acute Tox. 3; H311 Skin Irrit. 2; H315 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.
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.

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	5297469-00009	Date of first issue: 13.11.2019

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 so.
Evacuate area.

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
Date of first issue: 13.11.2019

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

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 Date of first issue: 13.11.2019

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/m ³ (OEB 2)	Internal
		Further information: DSEN		
		Wipe limit	100 µg/100 cm ²	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/m ³	2000/39/EC
		STEL	10 ppm 15 mg/m ³	2000/39/EC
Sodium hydroxide	1310-73-2	OEL- RL STEL/C	4 mg/m ³	ZA OEL
		Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents		

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

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 Date of first issue: 13.11.2019

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
Sodium hydroxide	Consumers	Inhalation	Long-term local effects	1 mg/m ³
	Workers	Inhalation	Long-term local effects	1 mg/m ³

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 weight (d.w.)

8.2 Exposure controls

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 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.

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	5297469-00009	Date of first issue: 13.11.2019

Hand protection		Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
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
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
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)		

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
Date of first issue: 13.11.2019

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

Flammability (liquids) : No data available
Molecular weight : 806,09 g/mol
Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

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

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
Date of first issue: 13.11.2019

Acute toxicity

Not classified based on available information.

Product:

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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): 8,3 mg/l
Exposure time: 30 min
Test atmosphere: dust/mist

Citric acid:

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): 645 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,5 - 1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): 670 mg/kg

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
Date of first issue: 13.11.2019

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
|| 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
|| Result : Irreversible effects on the eye

Hydrochloric acid:

|| Species : Bovine cornea
|| Method : OECD Test Guideline 437
|| 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.

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
Date of first issue: 13.11.2019

3-Mercaptopropane-1,2-diol:

Species : Rabbit
Result : No eye irritation

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

Sodium hydroxide:

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

3-Mercaptopropane-1,2-diol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : positive
Remarks : Based on data from similar materials

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Tulathromycin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 Date of first issue: 13.11.2019

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: Saacharomyces cerevisiae, mitotic recombination assay (in vitro)
 Result: negative

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

Carcinogenicity

Not classified based on available information.

Components:

Tulathromycin:

Carcinogenicity - Assessment : No data available

Hydrochloric acid:

Species : Rat
 Application Route : Inhalation
 Exposure time : 128 weeks
 Result : negative

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 Date of first issue: 13.11.2019

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 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
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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.
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Hydrochloric acid:

Assessment	:	May cause respiratory irritation.
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Citric acid:

Assessment	:	May cause respiratory irritation.
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STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 Date of first issue: 13.11.2019

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.

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

Citric acid:

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Tulathromycin:

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

Tulathromycin Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 5297469-00009 Date of last issue: 01.10.2022
 Date of first issue: 13.11.2019

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
 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

Citric acid:

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	5297469-00009	Date of first issue: 13.11.2019

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:

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded

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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12.3 Bioaccumulative potential

Components:

Tulathromycin:

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

Partition coefficient: n-octanol/water	:	log Pow: -1,72
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3-Mercaptopropane-1,2-diol:

Partition coefficient: n-octanol/water	:	log Pow: -0,84
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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
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Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	5297469-00009	Date of first issue: 13.11.2019

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. 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 Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	5297469-00009	Date of first issue: 13.11.2019

(Tulathromycin)

14.3 Transport hazard class(es)

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
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
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ADR

Environmentally hazardous	:	yes
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RID

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	5297469-00009	Date of first issue: 13.11.2019

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.

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.
H331	: Toxic if inhaled.
H335	: May cause respiratory irritation.
H361	: Suspected of damaging fertility or the unborn child.
H372	: Causes damage to organs through prolonged or repeated

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	5297469-00009	Date of first issue: 13.11.2019

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

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; NZIbC - 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; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
5.0	04.04.2023	5297469-00009	Date of first issue: 13.11.2019

- 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
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
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.

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