

Tulathromycin Formulation

Version 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
Date of first issue: 11/13/2019

SECTION 1. IDENTIFICATION

Product name : Tulathromycin Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Skin irritation : Category 2
Serious eye damage : Category 1
Skin sensitization : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity : Category 1 (Liver, Eye)
- repeated exposure (Oral)

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (Liver, Eye) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.

Tulathromycin Formulation

Version 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
 Date of first issue: 11/13/2019

P260 Do not breathe mist or vapors.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P272 Contaminated work clothing should not be allowed out of the workplace.
 P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
 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.
 P308 + P313 IF exposed or concerned: Get medical attention.
 P333 + P313 If skin irritation or rash occurs: Get medical attention.
 P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

- advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : 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.
- Most important symptoms and effects, both acute and delayed : Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye damage.
Suspected of damaging fertility or the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.
- 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).
- Notes to physician : Treat symptomatically and supportively.
-

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Chlorine compounds
Metal oxides
- 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.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

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

Tulathromycin Formulation

Version 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
 Date of first issue: 11/13/2019

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylene glycol	57-55-6	TWA (Vapour and aerosols)	50 ppm 155 mg/m ³	CA ON OEL
		TWA (aerosol)	10 mg/m ³	CA ON OEL
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	(c)	2 ppm 3 mg/m ³	CA AB OEL
		C	2 ppm	CA BC OEL
		C	2 ppm	CA QC OEL
		C	2 ppm	ACGIH
Sodium hydroxide	1310-73-2	(c)	2 mg/m ³	CA AB OEL
		C	2 mg/m ³	CA BC OEL
		C	2 mg/m ³	CA QC OEL
		C	2 mg/m ³	ACGIH

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

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/vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye 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.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Color	: Colorless to pale yellow
Odor	: slight
Odor 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
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
Density	: 1.07 g/cm ³

Tulathromycin Formulation

Version 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
Date of first issue: 11/13/2019

Solubility(ies)
Water solubility : > 1,000 mg/l

Partition coefficient: n-octanol/water : log Pow: -1.41

Autoignition 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.

Molecular weight : 806.09 g/mol

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

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

Tulathromycin Formulation

Version 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
Date of first issue: 11/13/2019

Method: Calculation method

Components:**Propylene glycol:**

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
Date of first issue: 11/13/2019

Skin corrosion/irritation

Causes skin irritation.

Components:

Propylene glycol:

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

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:

Propylene glycol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Tulathromycin:

Species : Rabbit
Result : Irreversible effects on the eye

Hydrochloric acid:

Species : Bovine cornea
Method : OECD Test Guideline 437

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

Result : Irreversible effects on the eye

Citric acid:

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

Sodium hydroxide:

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

3-Mercaptopropane-1,2-diol:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization**Skin sensitization**

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:**Propylene glycol:**

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Tulathromycin:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Assessment : May cause sensitization by skin contact.
Result : Causes sensitization.

Hydrochloric acid:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)
Routes of exposure : Skin contact
Result : negative

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

3-Mercaptopropane-1,2-diol:

Test Type	:	Maximization Test
Routes of exposure	:	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 sensitization rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Propylene glycol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

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

Citric acid:

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

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

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:

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

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.

Components:

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Tulathromycin:

Effects on fertility : Test Type: Fertility/early embryonic development

Tulathromycin Formulation

Version 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
Date of first issue: 11/13/2019

Species: Rat
Application Route: Oral
Fertility: NOAEL: 100 mg/kg body weight
Result: No significant adverse effects were reported

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

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.

Hydrochloric acid:

Assessment : May cause respiratory irritation.

Citric acid:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Causes damage to organs (Liver, Eye) through prolonged or repeated exposure if swallowed.

Components:**Tulathromycin:**

Routes of exposure : 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 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
Date of first issue: 11/13/2019

Repeated dose toxicity

Components:

Propylene glycol:

Species : Rat, male
NOAEL : $\geq 1,700$ mg/kg
Application Route : Ingestion
Exposure time : 2 y

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: Diarrhea, Nausea, Abdominal pain, Vomiting

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

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

Tulathromycin Formulation

Version 3.5 Revision Date: 10/01/2022 SDS Number: 5297455-00008 Date of last issue: 04/09/2022
Date of first issue: 11/13/2019

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: 41.1 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition of activated sludge
Method: OECD Test Guideline 209

EC10: 0.667 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition of activated sludge
Method: OECD Test Guideline 209

Citric acid:

Toxicity to fish : 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

Persistence and degradability**Components:****Propylene glycol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Tulathromycin:

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

Citric acid:

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

Bioaccumulative potential**Components:****Propylene glycol:**

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
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

International Regulations

UNRTDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tulathromycin)
Class : 9
Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Tulathromycin)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

	ty, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / C	: Ceiling limit
CA AB OEL / (c)	: ceiling occupational exposure limit
CA BC OEL / C	: ceiling limit
CA ON OEL / TWA	: Time-Weighted Average Limit (TWA)
CA QC OEL / C	: Ceiling

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

Revision Date : 10/01/2022
 Date format : mm/dd/yyyy

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

SAFETY DATA SHEET



Tulathromycin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	5297455-00008	Date of first issue: 11/13/2019

context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8