

Tulathromycin Formulation

Revision Date: SDS Number: Date of last issue: 04.04.2023 Version 5297457-00009 4.4 30.09.2023 Date of first issue: 13.11.2019

SECTION 1: IDENTIFICATION

Product name Tulathromycin Formulation

Manufacturer or supplier's details

Company MSD

: 91-105 Harpin Street Address

Bendigo 3550, Victoria Austrailia

Telephone 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address EHSDATASTEWARD@msd.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

Skin corrosion/irritation Category 2

Serious eye damage/eye irri-

tation

Category 1

Skin sensitisation Category 1

Reproductive toxicity Category 2

Specific target organ toxicity - : repeated exposure (Oral)

Category 1 (Liver, Eye)

GHS label elements

Hazard pictograms







Signal word Danger

H315 Causes skin irritation. Hazard statements

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



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

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.

and understood. P260 Do not breathe mist or vapours.

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 protec-

tion/ 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/ doctor.

P308 + P313 IF exposed or concerned: Get medical advice/

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Propylene glycol	57-55-6	>= 30 -< 60	
Tulathromycin	217500-96-4	>= 10 -< 30	
Hydrochloric acid	7647-01-0	>= 3 -< 5	
Citric acid	77-92-9	< 10	
Sodium hydroxide	1310-73-2	>= 1 -< 2	
3-Mercaptopropane-1,2-diol	96-27-5	< 1	

SECTION 4. FIRST AID MEASURES

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



Tulathromycin Formulation

Date of last issue: 04.04.2023 Version Revision Date: SDS Number: 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

vice 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.

First Aid responders should pay attention to self-protection, Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

Carbon oxides

Chlorine compounds

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Hazchem Code •3Z



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 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 absor-

bent.

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 deter-

mine 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 Advice on safe handling Use only with adequate ventilation.

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 as-

sessment

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.

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.



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

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.

Conditions for safe storage : Keep in properly labelled 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Propylene glycol	57-55-6	TWA (partic- ulate)	10 mg/m3	AU OEL		
		TWA (Total	150 ppm	AU OEL		
		(vapour and particles))	474 mg/m3			
Tulathromycin	217500-96-4	TWA	300 µg/m3 (OEB 2)	Internal		
	Further inform	Further information: DSEN				
		Wipe limit	100 μg/100 cm2	Internal		
Hydrochloric acid	7647-01-0	Peak limit	5 ppm 7.5 mg/m3	AU OEL		
		С	2 ppm	ACGIH		
Sodium hydroxide	1310-73-2	Peak limit	2 mg/m3	AU OEL		
		С	2 mg/m3	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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Combined particulates and acidic gas/vapour type



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

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 task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

SECTION 9. 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

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



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

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.

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 reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

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



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

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



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

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

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



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

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

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 sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Propylene glycol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

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



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

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

Chronic toxicity

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



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

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, miotic 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:

Propylene glycol:

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

Tulathromycin:

Carcinogenicity - Assess-

No data available

ment

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
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

Components:

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

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 develop-

ment

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 - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, and/or on development, based on animal experiments.

Citric acid:

Effects on foetal develop-

ment

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.



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

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:

Exposure routes : Oral Target Organs : Liver, Eye

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 yr

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



Tulathromycin Formulation

Revision Date: Date of last issue: 04.04.2023 Version SDS Number: 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

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

Ecotoxicity

Components:

Propylene glycol:

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

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

NOEC (Ceriodaphnia dubia (water flea)): 13,020 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 (Chron-

ic toxicity)

Exposure time: 7 d

Toxicity to microorganisms

NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

Tulathromycin:

LC50 (Pimephales promelas (fathead minnow)): 4 mg/l Toxicity to fish

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



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

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

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



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

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:

Partition coefficient: n- : log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

Tulathromycin:

Partition coefficient: n- : log Pow: -1.41

octanol/water pH: 7

Citric acid:

Partition coefficient: n-

: log Pow: -1.72

octanol/water

3-Mercaptopropane-1,2-diol:

Partition coefficient: n- : log Pow: -0.84

octanol/water

Mobility in soilNo data available

Other adverse effects

No data available



Tulathromycin Formulation

Date of last issue: 04.04.2023 Version **Revision Date:** SDS Number: 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling 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

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

(Tulathromycin)

Class 9 Ш Packing group Labels 9 Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

Environmentally hazardous substance, liquid, n.o.s. Proper shipping name

(Tulathromycin)

Class 9 Packing group Ш

Labels Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-964

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN 3082 UN number

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

964

(Tulathromycin)

Class 9 Ш Packing group Labels 9 **EmS Code** F-A, S-F Marine pollutant yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

ADG



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.4 30.09.2023 5297457-00009 Date of first issue: 13.11.2019

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : •3Z
Environmentally hazardous : yes

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Prohibition/Licensing Requirements : There is no applicable prohibition,

authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

tions.

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

IECSC : not determined

DSL : not determined

AICS : not determined

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date : 30.09.2023

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

AU OEL : Australia. Workplace Exposure Standards for Airborne Con-

taminants.



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.4
 30.09.2023
 5297457-00009
 Date of first issue: 13.11.2019

ACGIH / C : Ceiling limit

AU OEL / TWA : Exposure standard - time weighted average

AU OEL / Peak limit : Exposure standard - peak

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect 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

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.

AU / EN