

Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

SECTION 1. IDENTIFICATION

Product identifier : Tulathromycin Formulation

Other means of identification : AROVYN INJECTABLE SOLUTION (90779)

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

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 in accordance with ABNT NBR 14725 Standard

Skin irritation : Category 2

Serious eye damage : Category 1

Skin sensitization : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure (Oral)

Category 1 (Liver, Eye)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms









Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 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 (Liver, Eye) through prolonged

or repeated exposure if swallowed.

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.

P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

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/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Tulathromycin	217500-96-4	Acute Tox. (Oral), 5 Acute Tox. (Dermal), 5 Eye Dam., 1 Skin Sens., 1 Repr., 2 STOT RE, (Oral)(Liver, Eye), 1 Aquatic Acute, 1 Aquatic Chronic, 1	>= 10 -< 20



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

Hydrochloric acid	7647-01-0	Met. Corr., 1 Skin Corr., 1A Eye Dam., 1 STOT SE, 3	>= 3 -< 5
Citric acid	77-92-9	Eye Irrit., 2A STOT SE, 3	>= 1 -< 5
Sodium hydroxide	1310-73-2	Met. Corr., 1 Skin Corr., 1A Eye Dam., 1	>=1-<2
3-Mercaptopropane-1,2-diol	96-27-5	Acute Tox. (Oral), 4 Acute Tox. (Dermal), 3 Skin Irrit., 2 Eye Irrit., 2A Skin Sens., 1B Aquatic Acute, 3	>= 0,25 -< 1

SECTION 4. 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.

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



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

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 prod-

ucts

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

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

Personal precautions, protective equipment and emer-

gency 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.



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

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.

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.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Tulathromycin	217500-96-4	TWA	300 μg/m3 (OEB 2)	Internal	
	Further information: DSEN				
		Wipe limit	100 μg/100 cm2	Internal	
Hydrochloric acid	7647-01-0	С	2 ppm	ACGIH	
Sodium hydroxide	1310-73-2	С	2 mg/m³	ACGIH	



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

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.

: Combined particulates and acidic gas/vapor type

Filter 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 task being performed (e.g., sleevelets, apron, gauntlets, dispensely suits) to sucid expensely suits as a suits of the suits are suits.

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : 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



Tulathromycin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 5297456-00014 Date of first issue: 13.11.2019 6.0

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

1,07 g/cm³ Density

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 characteristics

Particle size Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

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



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5.000 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): 648 mg/kg

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

Skin corrosion/irritation

Causes skin irritation.

Components:

Tulathromycin:



Tulathromycin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 5297456-00014 Date of first issue: 13.11.2019 6.0

Species Result Rabbit

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

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

Result Irritation to eyes, reversing within 21 days



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

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

3-Mercaptopropane-1,2-diol:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization

rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Tulathromycin:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay)



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

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, 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

3-Mercaptopropane-1,2-diol:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Tulathromycin:

Carcinogenicity - Assess-

: No data available

ment



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

Hydrochloric acid:

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

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:

Tulathromycin:

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

Species: Rat

Application Route: Oral

Fertility: NOAEL: 100 mg/kg body weight

Result: No significant adverse effects were reported

Effects on 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 - As-

sessment

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

3-Mercaptopropane-1,2-diol:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

Remarks: Based on data from similar materials

STOT-single exposure

Not classified based on available information.

Components:

Tulathromycin:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

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 con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Tulathromycin:

Species: RatNOAEL: 5 mg/kgApplication Route: OralExposure time: 3 MonthsTarget 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



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

Application Route : Ingestion Exposure time : 10 Days

3-Mercaptopropane-1,2-diol:

Species : Rat

LOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 55 Days

Method : OECD Test Guideline 422

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Tulathromycin:

Ingestion : Symptoms: Diarrhea, Nausea, Abdominal pain, Vomiting

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Tulathromycin:

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

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 0,044

mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0,014

mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae): 0,0023 mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201



Tulathromycin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 5297456-00014 Date of first issue: 13.11.2019 6.0

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 tox- :

M-Factor (Chronic aquatic

Toxicity to microorganisms

toxicity)

EC50: 41,1 mg/l

100

100

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:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 10 - 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Raphidocelis subcapitata (freshwater green alga)): >

10 - 100 ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials



Tulathromycin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 6.0
 28.09.2024
 5297456-00014
 Date of first issue: 13.11.2019

EC10 (Raphidocelis subcapitata (freshwater green alga)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (activated sludge): > 1 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Persistence and degradability

Components:

Tulathromycin:

Biodegradability : Result: Not readily biodegradable.

Exposure time: 29 d

Method: OECD Test Guideline 301B

Citric acid:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

3-Mercaptopropane-1,2-diol:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

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 Method: OECD Test Guideline 117

Mobility in soil

No data available

Other adverse effects

No data available



Tulathromycin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 5297456-00014 Date of first issue: 13.11.2019 6.0

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

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 Ш Labels 9 Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

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

(Tulathromycin)

9 Class Ш Packing group

Labels Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(Tulathromycin)

Class 9 Packing group Ш 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.

Domestic regulation

ANTT

UN number UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.



Tulathromycin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 5297456-00014 Date of first issue: 13.11.2019 6.0

(Tulathromycin)

Class 9 Packing group Ш Labels 9 Hazard Identification Number 90

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

National List of Carcinogenic Agents for Humans -Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal Sodium hydroxide

Police

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

IECSC not determined

DSL not determined

AICS not determined

SECTION 16. OTHER INFORMATION

Revision Date 28.09.2024 Date format dd.mm.yyyy

Further information

Sources of key data used to

compile the Material Safety

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Data Sheet

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Internal technical data, data from raw material SDSs, OECD

Full text of other abbreviations

ACGIH USA. ACGIH Threshold Limit Values (TLV)

ACGIH / C Ceiling limit

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;



Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 5297456-00014 Date of first issue: 13.11.2019

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.

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