

Tulathromycin Formulation

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 5297467-00012 Date of first issue: 13.11.2019

Section 1: Identification

Product identifier : Tulathromycin Formulation

Other means of identifica-

tion

: AROVYN INJECTABLE SOLUTION (90779)

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive

Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

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)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS Label elements, including precautionary statements



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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.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

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.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection/ hearing 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.

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



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Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Tulathromycin	217500-96-4	>= 10 -< 20	
Hydrochloric acid	7647-01-0	>= 3 -< 5	
Citric acid	77-92-9	>= 1 -< 10	
Sodium hydroxide	1310-73-2	>= 1 -< 2	
3-Mercaptopropane-1,2-diol	96-27-5	>= 0.1 -< 1	

Section 4: First-aid measures

Description of necessary first-aid measures

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

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

Risks Causes skin irritation.

> May cause an allergic skin reaction. Causes serious eye damage.

Suspected of damaging fertility or the unborn child.

Causes damage to organs through prolonged or repeated

exposure 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).

Indication of any immediate medical attention and special treatment needed

Treatment Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media



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Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides
Chlorine compounds

Metal oxides

Special protective actions for fire-fighters

Special protective equipment :

for firefighters

Specific extinguishing meth-

ods

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

Use personal protective equipment.

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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable 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



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certain local or national requirements.

Section 7: Handling and storage

Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure 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.

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, including any incompatibilities

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

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	



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		exposure)	concentration		
Tulathromycin	217500-96-4	TWA	300 μg/m3 (OEB	Internal	
-			2)		
	Further information: DSEN				
		Wipe limit	100 µg/100 cm2	Internal	
Hydrochloric acid	7647-01-0	PEL (short	5 ppm	SG OEL	
		term)	7.5 mg/m3		
		С	2 ppm	ACGIH	
Sodium hydroxide	1310-73-2	PEL (short	2 mg/m3	SG OEL	
-		term)			
		С	2 mg/m3	ACGIH	

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

Wear safety glasses with side shields or goggles. Eye/face protection

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.

Work uniform or laboratory coat. Skin protection

> 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.

Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and acidic gas/vapour type

Filter type

Material

Hand protection

Chemical-resistant gloves

Remarks Consider double gloving.

Section 9: Physical and chemical properties

Appearance liquid

Colour Colorless to pale yellow

Odour slight



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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

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 characteristics



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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- : Can react with strong oxidizing agents.

tions

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

Hazardous decomposition : No hazardous decomposition products are known.

products

Section 11: Toxicological information

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

Tulathromycin:

Acute oral toxicity : LD50 (Dog): > 1,000 mg/kg

Target Organs: Gastrointestinal tract

LD50 (Rat): > 2,000 mg/kg

Target Organs: Gastrointestinal tract

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Target Organs: Gastrointestinal tract

Hydrochloric acid:

Acute inhalation toxicity : LC50 (Rat): 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



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Assessment: The substance or mixture has no acute dermal

toxicity

Sodium hydroxide:

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

3-Mercaptopropane-1,2-diol:

Acute oral toxicity : LD50 (Rat): 648 mg/kg

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

Skin corrosion/irritation

Causes skin irritation.

Components:

Tulathromycin:

Species : Rabbit

Result : No skin irritation

Hydrochloric acid:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 431

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



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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 : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Tulathromycin:

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

Assessment : May cause sensitisation by skin contact.

Result : Causes sensitisation.

Hydrochloric acid:

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

Method : OECD Test Guideline 406

Result : negative

Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Result : negative



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3-Mercaptopropane-1,2-diol:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Tulathromycin:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

cytogenetic assay) Species: Rat Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Hydrochloric acid:

Genotoxicity in vitro : Test Type: 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



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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-

ment

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:

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.



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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

3-Mercaptopropane-1,2-diol:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

Components:

Tulathromycin:

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

organ toxicant, single exposure.

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.



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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:

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

3-Mercaptopropane-1,2-diol:

Species : Rat

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

Method : OECD Test Guideline 422

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Tulathromycin:



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

Section 12: Ecological information

Toxicity

Components:

Tulathromycin:

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

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.044

mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0.014

mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae): 0.0023 mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Anabaena flos-aquae): 0.00035 mg/l

End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Synechococcus leopoliensis (blue-green algae)):

0.0028 mg/l End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Synechococcus leopoliensis (blue-green algae)):

0.0012 mg/l End point: Growth Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 100



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icity)

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

100

EC50: 41.1 mg/l

Test Type: Respiration inhibition of activated sludge

Method: OECD Test Guideline 209

EC10: 0.667 mg/l Exposure time: 3 h

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 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

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

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

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

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials



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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

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.



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Section 14: Transport information

International Regulations

UNRTDG

UN number : UN 3082

UN proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

Transport hazard class(es) : 9
Packing group : III
Labels : 9
Environmental hazards : yes

IATA-DGR

UN/ID No. : UN 3082

UN proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Tulathromycin)

Transport hazard class(es) : 9
Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen- : 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tulathromycin)

Transport hazard class(es) : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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 specific for the product in question



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Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable

Regulations

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

IECSC : not determined

DSL : not determined

AICS : not determined

Section 16: Other information

Revision Date : 06.07.2024

Further information

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-

Not applicable

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

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore. Workplace Safety and Health (General Provisions)

Regulations - First Schedule Permissible Exposure Limits of

Toxic Substances.

ACGIH / C : Ceiling limit

SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

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 Chemi-



Tulathromycin Formulation

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cal 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.

SG / EN