

**Tulathromycin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2024/12/04
13.0	2025/04/14	5297463-00018	Date of first issue: 2019/11/13

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name : Tulathromycin Formulation

Other means of identification : AROVYN INJECTABLE SOLUTION (90779)

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : 1-908-423-6000

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product

Restrictions on use : Not applicable

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**2. HAZARDS IDENTIFICATION****GHS classification of chemical product**

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : 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**

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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 protection/ 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 advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
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.

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Propylene glycol	57-55-6	$\geq 50 - < 60$	2-234
Tulathromycin	217500-96-4	$\geq 10 - < 20$	-
Hydrochloric acid	7647-01-0	$\leq 3$	1-215
Citric acid	77-92-9	$\geq 1 - < 10$	2-1318
Sodium hydroxide	1310-73-2	$\leq 1$	1-410
3-Mercaptopropane-1,2-diol	96-27-5	$\geq 0.25 - < 1$	9-805

## 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.

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**5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Metal oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

**6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

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mine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**7. HANDLING AND STORAGE****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.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment.   |
| Avoidance of contact    | : | Oxidizing agents   |
| Hygiene measures        | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>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. |

**Storage**

- |                             |   |  |
|-----------------------------|---|--|
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations. |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents  |
| Packaging material          | : | Unsuitable material: None known.   |

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Threshold limit value and permissible exposure limits for each component in the work environment**

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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Tulathromycin	217500-96-4	TWA	300 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Hydrochloric acid	7647-01-0	OEL-C	2 ppm 3 mg/m <sup>3</sup>	JP OEL JSH
		C	2 ppm	ACGIH
Sodium hydroxide	1310-73-2	OEL-C	2 mg/m <sup>3</sup>	JP OEL JSH
		C	2 mg/m <sup>3</sup>	ACGIH

**Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and acidic gas/vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.  
Impermeable protective gloves

Eye protection : Wear safety glasses with side shields or goggles.

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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, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state	: liquid
Colour	: Colorless to pale yellow
Odour	: slight
Odour Threshold	: No data available
Melting point/freezing point	: 190 - 192 °C
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Lower explosion limit and upper explosion limit / flammability limit	
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: No data available
Decomposition temperature	: No data available
pH	: 5.1 - 5.7
Evaporation rate	: No data available
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Solubility(ies)	
Water solubility	: > 1,000 mg/l

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Partition coefficient: n-octanol/water	:	log Pow: -1.41
Vapour pressure	:	No data available
Density and / or relative density	:	
Relative density	:	No data available
Density	:	1.07 g/cm <sup>3</sup>
Relative vapour density	:	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

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**10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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**Acute toxicity**

Not classified based on available information.

**Product:**

Acute dermal toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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**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, male): 8.3 mg/l Exposure time: 30 min Test atmosphere: dust/mist Assessment: Corrosive to the respiratory tract. Remarks: No test guideline followed
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**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.
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**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.

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**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
Remarks	: The test was conducted according to guideline
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
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**3-Mercaptopropane-1,2-diol:**

Species	: Rabbit
Result	: Skin irritation

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:****Propylene glycol:**

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

**Tulathromycin:**

Species	: Rabbit
Result	: Irreversible effects on the eye

**Hydrochloric acid:**

Species	: Bovine cornea
Method	: OECD Test Guideline 437

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Remarks : The test was conducted according to guideline

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:****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 : Human repeat insult patch test (HRIPT)  
Exposure routes : Skin contact  
Species : Humans  
Result : negative

**Sodium hydroxide:**

Test Type : Human repeat insult patch test (HRIPT)

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Exposure routes	: Skin contact
Result	: negative

**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
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**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Propylene glycol:**

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

**Tulathromycin:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Result: negative
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

**Hydrochloric acid:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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Remarks: No test guideline followed

**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
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**Carcinogenicity**

Not classified based on available information.

**Components:****Propylene glycol:**

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

**Tulathromycin:**

Carcinogenicity - Assessment	: No data available
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**Hydrochloric acid:**

Species	: Rat, male
Application Route	: inhalation (gas)
Exposure time	: 128 weeks
Result	: negative
Remarks	: No test guideline followed

**Reproductive toxicity**

Suspected of damaging fertility or the unborn child.

**Components:****Propylene glycol:**

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative
Effects on foetal development	: 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 development	: Test Type: Embryo-foetal development Species: Rat Application Route: Oral General Toxicity Maternal: NOAEL: 15 mg/kg body weight Teratogenicity: NOAEL: 15 mg/kg body weight Result: Postimplantation loss.  Test Type: Embryo-foetal development Application Route: Oral General Toxicity Maternal: NOAEL: 15 mg/kg body weight Teratogenicity: NOAEL: 15 mg/kg body weight Result: Maternal toxicity observed.
Reproductive toxicity - Assessment	: Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

**Citric acid:**

Effects on foetal development	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion
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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 development : 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.

**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 concentrations of 10 mg/kg bw or less.

**Repeated dose toxicity****Components:****Propylene glycol:**

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

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**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

**Hydrochloric acid:**

Species	: Rat, male
LOAEL	: > 12.5 mg/kg
Application Route	: Ingestion
Exposure time	: 2 yr
Method	: OECD Test Guideline 453
Remarks	: The test was conducted equivalent or similar to guideline Based on data from similar materials

**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.



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## Experience with human exposure

Components:

## Tulathromycin:

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

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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

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EC50 (Anabaena flos-aquae): 0.0023 mg/l  
End point: Growth  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC10 (Anabaena flos-aquae): 0.00035 mg/l  
End point: Growth  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0028 mg/l  
End point: Growth  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC10 (Synechococcus leopoliensis (blue-green algae)): 0.0012 mg/l  
End point: Growth  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100

M-Factor (Chronic aquatic toxicity) : 100

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

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

**Hydrochloric acid:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

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	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: The test was conducted according to guideline Based on data from similar materials
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): > 1 mg/l Exposure time: 33 d Method: OECD Test Guideline 210 Remarks: The test was conducted equivalent or similar to guideline Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia pulex (Water flea)): > 1 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: The test was conducted equivalent or similar to guideline Based on data from similar materials
Toxicity to microorganisms	: EC10 (activated sludge): > 1 mg/l Exposure time: 3 h Remarks: Based on data from similar materials

**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

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	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:****Propylene glycol:**

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

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

Biodegradability	: Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d Method: OECD Test Guideline 301B
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**3-Mercaptopropane-1,2-diol:**

Biodegradability	: Result: Readily biodegradable. Remarks: Based on data from similar materials
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**Bioaccumulative potential****Components:****Propylene glycol:**

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

Partition coefficient: n-octanol/water	: log Pow: -1.41 pH: 7
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**Citric acid:**

Partition coefficient: n-octanol/water : log Pow: -1.72

**3-Mercaptopropane-1,2-diol:**

Partition coefficient: n-octanol/water : log Pow: -0.84  
Method: OECD Test Guideline 117

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

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

**IATA-DGR**

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

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**IMDG-Code**

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

Refer to section 15 for specific national regulation.

**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.

<b>ERG Code</b>	:	171
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**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106

**Industrial Safety and Health Law****Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

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**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

Chemical name	Concentration (%)	Remarks
Propylene glycol	$\geq 50$ - $< 60$	From April 1st, 2025
Hydrogen chloride	$\leq 3$	-
Sodium hydroxide	$\leq 1$	-

**Substances Subject to be Indicated Names**

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

Chemical name	Remarks
Propylene glycol	From April 1st, 2025
Hydrogen chloride	-
Sodium hydroxide	-

**Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

Chemical name
Sodium hydroxide

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances - Group 3 Substance**

Chemical name
hydrogen chloride

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

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**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

IECSC : not determined

DSL : not determined

AICS : not determined

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**16. OTHER INFORMATION**

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**Further information**

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

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits



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ACGIH / C : Ceiling limit  
JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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.

JP / EN