SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Tulathromycin Formulation

SECTION 1. IDENTIFICATION

Product name : Tulathromycin Formulation

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

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
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)

GHS label elements
Hazard pictograms :

Signal Word : Danger

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

Precautionary Statements :
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>50</td>
</tr>
<tr>
<td>Tulathromycin</td>
<td>217500-96-4</td>
<td>10</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>7647-01-0</td>
<td>&lt;= 3</td>
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<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>2</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&lt;= 1</td>
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<tr>
<td>3-Mercaptopropane-1,2-diol</td>
<td>96-27-5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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

Suitable extinguishing media: Water spray 
Alcohol-resistant foam 
Carbon dioxide (CO2) 
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: 
Carbon oxides 
Chlorine compounds 
Metal oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. 
Use water spray to cool unopened containers. 
Remove undamaged containers from fire area if it is safe to do so. 
Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. 
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. 
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. 
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- Use only with adequate ventilation.
- 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.

Advice on safe handling:
- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Conditions for safe storage:
- 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 | Control parameters / Permissible concentration | Basis |
--- | --- | --- | --- | --- |
Propylene glycol | 57-55-6 | TWA | 10 mg/m³ | US WEEL |
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 | C | 2 ppm | ACGIH |
| | | C | 5 ppm | NIOSH REL |
| | | 7 mg/m³ | |
| | | C | 5 ppm | OSHA Z-1 |
| | | 7 mg/m³ | |
Sodium hydroxide | 1310-73-2 | C | 2 mg/m³ | ACGIH |
| | | C | 2 mg/m³ | NIOSH REL |
| | | TWA | 2 mg/m³ | OSHA Z-1 |

**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**

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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
Hygiene measures

- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Contaminated work clothing should not be allowed out of the workplace.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Colorless to pale yellow</td>
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<tr>
<td>Odor</td>
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<td>Odor Threshold</td>
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<td>pH</td>
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<td>Melting point/freezing point</td>
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<td>Initial boiling point and boiling range</td>
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<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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<td>Flammability (solid, gas)</td>
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<tr>
<td>Flammability (liquids)</td>
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<tr>
<td>Upper explosion limit / Upper flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<tr>
<td>Vapor pressure</td>
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<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
## Density
- 1.07 g/cm³

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

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

## Autoignition temperature
- **No data available**

## Decomposition temperature
- **No data available**

## Viscosity
- **Viscosity, kinematic**: No data available

## Explosive properties
- **Not explosive**

## Oxidizing properties
- The substance or mixture is not classified as oxidizing.

## Molecular weight
- 806.09 g/mol

## Particle size
- Not applicable

### SECTION 10. STABILITY AND REACTIVITY

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

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure
- **Inhalation**
- **Skin contact**
- **Ingestion**
- **Eye contact**

#### Acute toxicity
- Not classified based on available information.

**Product:**
- **Acute oral toxicity**: Acute toxicity estimate: > 5,000 mg/kg
  - Method: Calculation method
- **Acute inhalation toxicity**: Acute toxicity estimate: 100.01 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

**Propylene glycol:**
- Acute oral toxicity: LD50 (Rat): 22,000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 44.9 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity

**Tulathromycin:**
- Acute oral toxicity: LD50 (Dog): > 1,000 mg/kg
  - Target Organs: Gastrointestinal tract
  - LD50 (Rat): > 2,000 mg/kg
  - Target Organs: Gastrointestinal tract
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  - Target Organs: Gastrointestinal tract

**Hydrochloric acid:**
- Acute inhalation toxicity: LC50 (Rat): 8.3 mg/l
  - Exposure time: 30 min
  - Test atmosphere: dust/mist

**Citric acid:**
- Acute oral toxicity: LD50 (Mouse): 5,400 mg/kg
- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity

**Sodium hydroxide:**
- Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.

**3-Mercaptopropane-1,2-diol:**
- Acute oral toxicity: LD50 (Rat): 645 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 0.5 - 1 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
Remarks: Based on data from similar materials

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

**Skin corrosion/irritation**
Causes skin irritation.

**Components:**

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

**Tulathromycin:**
Species  :  Rabbit
Result  :  No skin irritation

**Hydrochloric acid:**
Species  :  reconstructed human epidermis (RhE)
Method  :  OECD Test Guideline 431
Result  :  Corrosive after 3 minutes or less of exposure

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

**Sodium hydroxide:**
Result  :  Corrosive after 3 minutes or less of exposure

**3-Mercaptopropane-1,2-diol:**
Species  :  Rabbit
Result  :  Skin irritation

**Serious eye damage/eye irritation**
Causes serious eye damage.

**Components:**

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

**Tulathromycin:**
Species  :  Rabbit
Result  :  Irreversible effects on the eye
Hydrochloric acid:
Species: Bovine cornea
Method: OECD Test Guideline 437
Result: Irreversible effects on the eye

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

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

3-Mercaptopropane-1,2-diol:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization
Skin sensitization
May cause an allergic skin reaction.
Respiratory sensitization
Not classified based on available information.

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

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

Hydrochloric acid:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
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Version: 3.6
Revision Date: 09/30/2023
SDS Number: 5297468-00010
Date of last issue: 04/04/2023
Date of first issue: 11/13/2019

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

3-Mercaptopropane-1,2-diol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: positive
Remarks: Based on data from similar materials
Assessment: Probability or evidence of low to moderate skin sensitization rate in humans

Germ cell mutagenicity
Not classified based on available information.

Components:

Propylene glycol:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Tulathromycin:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Result: negative

Germ cell mutagenicity - Assessment:
Weight of evidence does not support classification as a germ cell mutagen.
Hydrochloric acid:
Genotoxicity in vitro: Test Type: Saacharomyces cerevisiae, miotic recombination assay (in vitro); Result: negative

Citric acid:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES); Result: negative
Test Type: in vitro micronucleus test; Result: positive
Test Type: Bacterial reverse mutation assay (AMES); Result: negative
Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis); Species: Rat; Application Route: Ingestion; Result: negative

Carcinogenicity
Not classified based on available information.

Components:

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

Tulathromycin:
Carcinogenicity - Assessment: No data available

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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
## Reproductive toxicity
Suspected of damaging fertility or the unborn child.

### Components:

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

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

#### Tulathromycin:
Effects on fertility:
- **Test Type:** Fertility/early embryonic development
- **Species:** Rat
- **Application Route:** Oral
- **Fertility:** NOAEL: 100 mg/kg body weight
- **Result:** No significant adverse effects were reported

Effects on fetal development:
- **Test Type:** Embryo-fetal development
- **Species:** Rat
- **Application Route:** Oral
- **General Toxicity Maternal:** NOAEL: 15 mg/kg body weight
- **Teratogenicity:** NOAEL: 15 mg/kg body weight
- **Result:** Postimplantation loss.

Test Type: Embryo-fetal development
- **Application Route:** Oral
- **General Toxicity Maternal:** NOAEL: 15 mg/kg body weight
- **Teratogenicity:** NOAEL: 15 mg/kg body weight
- **Result:** Maternal toxicity observed.

Reproductive toxicity - Assessment:
- Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

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

### STOT-single exposure
Not classified based on available information.

#### Components:

#### Tulathromycin:
Assessment:
The substance or mixture is not classified as specific target
organ toxicant, single exposure.

**Hydrochloric acid:**
Assessment : May cause respiratory irritation.

**Citric acid:**
Assessment : May cause respiratory irritation.

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

**Components:**

**Tulathromycin:**
**Routes of exposure** : Oral
**Target Organs** : Liver, Eye
**Assessment** : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

**Repeated dose toxicity**

**Components:**

**Propylene glycol:**
**Species** : Rat, male
**NOAEL** : >= 1,700 mg/kg
**Application Route** : Ingestion
**Exposure time** : 2 y

**Tulathromycin:**
**Species** : Rat
**NOAEL** : 5 mg/kg
**Application Route** : Oral
**Exposure time** : 3 Months
**Target Organs** : Liver
**Symptoms** : Liver disorders

**Species** : Dog
**NOAEL** : 5 mg/kg
**Application Route** : Oral
**Exposure time** : 3 Months
**Target Organs** : Liver, Eye
**Symptoms** : Liver disorders, Eye disease

**Citric acid:**
**Species** : Rat
**NOAEL** : 4,000 mg/kg
**LOAEL** : 8,000 mg/kg
**Application Route** : Ingestion
**Exposure time** : 10 Days
Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Tulathromycin:

Ingestion  
Symptoms: Diarrhea, Nausea, Abdominal pain, Vomiting

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylene glycol:

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

Toxicity to daphnia and other aquatic invertebrates  
EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants  
ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)  
NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l  
Exposure time: 7 d

Toxicity to microorganisms  
NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h

Tulathromycin:

Toxicity to fish  
LC50 (Pimephales promelas (fathead minnow)): 4 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates  
EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants  
EC50 (Pseudokirchneriella subcapitata (green algae)): 0.044 mg/l  
End point: Growth  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0.014 mg/l  
End point: Growth  
Exposure time: 72 h
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Method: OECD Test Guideline 201
EC50 (Anabaena flos-aquae): 0.0023 mg/l
End point: Growth
Exposure time: 72 h
Method: OECD Test Guideline 201

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

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

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

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

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

Citric acid:
Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 1,535 mg/l
Exposure time: 24 h

3-Mercaptopropane-1,2-diol:

Ecotoxicology Assessment
Acute aquatic toxicity:
Toxic effects cannot be excluded

Chronic aquatic toxicity:
Toxic effects cannot be excluded

Persistence and degradability

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

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

**Citric acid:**

**Bioaccumulative potential**

**Components:**

**Propylene glycol:**

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

**Citric acid:**
Partition coefficient: n-octanol/water: log Pow: -1.72

**3-Mercaptopropane-1,2-diol:**
Partition coefficient: n-octanol/water: log Pow: -0.84

**Mobility in soil**
No data available

**Other adverse effects**
No data available

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**
Waste from residues: Dispose of in accordance with local regulations. 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.
SECTION 14. TRANSPORT INFORMATION

International Regulations

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

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.

Domestic regulation

49 CFR
UN/ID/NA number: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Tulathromycin)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Tulathromycin)
Remarks: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it
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according to the OSHA Hazard Communication Standard

Tulathromycin Formulation

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Date of last issue: 04/04/2023
Date of first issue: 11/13/2019

may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>1000</td>
<td>100000</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>7647-01-0</td>
<td>5000</td>
<td>166666</td>
</tr>
</tbody>
</table>

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Respiratory or skin sensitization
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)
- Skin corrosion or irritation
- Serious eye damage or eye irritation

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Propylene glycol 57-55-6
- Water 7732-18-5
- Tulathromycin 217500-96-4
- Hydrochloric acid 7647-01-0
- Sodium hydroxide 1310-73-2

California List of Hazardous Substances
- Hydrochloric acid 7647-01-0
- Sodium hydroxide 1310-73-2

California Permissible Exposure Limits for Chemical Contaminants
- Hydrochloric acid 7647-01-0
- Sodium hydroxide 1310-73-2

California List of Acutely Hazardous Chemicals, Toxics and Reactives
- Hydrochloric acid 7647-01-0

The ingredients of this product are reported in the following inventories:
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:  

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

HMIS® IV:  

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / C : Ceiling limit
NIOSH REL / C : Ceiling value not be exceeded at any time.
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-1 / C : Ceiling
US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TCEI - 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


Revision Date: 09/30/2023

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.

US / Z8