SAFETY DATA SHEET

Tulathromycin Formulation

SECTION 1. IDENTIFICATION

Product name: Tulathromycin Formulation
Other means of identification: No data available

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 Hazardous Products Regulations
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: [Pictograms depicting hazard symbols]
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.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and 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.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 IF skin irritation or rash occurs: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>1,2-Propanediol</td>
<td>57-55-6</td>
<td>50</td>
</tr>
<tr>
<td>Tulathromycin</td>
<td>No data available</td>
<td>217500-96-4</td>
<td>10</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>No data available</td>
<td>7647-01-0</td>
<td>&lt;= 3</td>
</tr>
<tr>
<td>Citric acid</td>
<td>2-hydroxypropane-1,2,3-tricarboxylic acid</td>
<td>77-92-9</td>
<td>2</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>Caustic soda</td>
<td>1310-73-2</td>
<td>&lt;= 1</td>
</tr>
<tr>
<td>3-Mercaptopropane-1,2-diol</td>
<td>Thioglycerol</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 help immediately and show the...
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.

Advice on safe handling

Do not get on skin or clothing. Do not breathe mist or vapors. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage

Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid

Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases
SAFETY DATA SHEET

Tulathromycin Formulation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (Vapour and aerosols)</td>
<td>50 ppm  155 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td>Tulathromycin</td>
<td>217500-96-4</td>
<td>TWA</td>
<td>300 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: DSEN</td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>7647-01-0</td>
<td>(c)</td>
<td>2 ppm  3 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>(c)</td>
<td>2 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures:
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

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

Filter type:
Combined particulates and acidic gas/vapor type

Hand protection:
Material: Chemical-resistant gloves
Remarks: Consider double gloving.
Eye protection:
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection:
Work uniform or laboratory coat.
Additional body garments should be used based upon the
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 degowned and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: liquid
- **Color**: Colorless to pale yellow
- **Odor**: slight
- **Odor Threshold**: No data available
- **pH**: 5.1 - 5.7
- **Melting point/freezing point**: 190 - 192 °C
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Relative density**: No data available
- **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: > 2,000 mg/kg
  - Method: Calculation method
- **Acute inhalation toxicity**: Acute toxicity estimate: > 5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: Calculation method
- **Acute dermal toxicity**: Acute toxicity estimate: > 2,000 mg/kg
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

**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)
SAFETY DATA SHEET

Tulathromycin Formulation

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

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
<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposition time: 48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposition time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposition time: 7 d</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>NOEC (Pseudomonas putida): &gt; 20,000 mg/l Exposition time: 18 h</td>
</tr>
</tbody>
</table>

**Tulathromycin:**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Pimephales promelas (fathead minnow)): 4 mg/l Exposition time: 96 h Method: OECD Test Guideline 203</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposition time: 48 h Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 0.044 mg/l End point: Growth Exposition time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC10 (Pseudokirchneriella subcapitata (green algae)): 0.014 mg/l End point: Growth Exposition time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC50 (Anabaena flos-aquae): 0.0023 mg/l End point: Growth Exposition time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC10 (Anabaena flos-aquae): 0.00035 mg/l End point: Growth Exposition time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0028 mg/l End point: Growth Exposition time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC10 (Synechococcus leopoliensis (blue-green algae)): 0.0012 mg/l End point: Growth Exposition time: 72 h Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>
Tulathromycin Formulation

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:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Propylene glycol:
SAFETY DATA SHEET

Tulathromycin Formulation

Partition coefficient: n-octanol/water: log Pow: -1.07

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

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

TDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tulathromycin)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes (Tulathromycin)

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

The ingredients of this product are reported in the following inventories:
IECSC : not determined
DSL : not determined
AICS : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
SAFETY DATA SHEET

Tulathromycin Formulation

Version: 3.6  
Revision Date: 04/04/2023  
SDS Number: 5297455-00009  
Date of last issue: 10/01/2022  
Date of first issue: 11/13/2019

CA QC OEL: Québec. Regulation respecting occupational health and safety; Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / C: Ceiling limit
CA AB OEL / (c): ceiling occupational exposure limit
CA BC OEL / C: ceiling limit
CA ON OEL / TWA: Time-Weighted Average Limit (TWA)
CA QC OEL / C: Ceiling


Revision Date: 04/04/2023
Date format: mm/dd/yyyy

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.

CA / Z8