SAFETY DATA SHEET

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.
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 must 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 soap and 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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</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>
</tr>
<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>
</tr>
<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.

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

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</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
</tbody>
</table>
Tulathromycin Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>TWA</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tulathromycin</td>
<td>217500-96-4</td>
<td>300 µg/m³ (OEB 2)</td>
<td></td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>7647-01-0</td>
<td>2 ppm</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>2 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Further information: DSEN

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric acid</td>
<td>7647-01-0</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>2 ppm</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

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 task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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><strong>Appearance</strong></td>
<td>liquid</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Colorless to pale yellow</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>slight</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>5.1 - 5.7</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>374 - 378 °F / 190 - 192 °C</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative vapor density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>1.07 g/cm³</td>
</tr>
<tr>
<td><strong>Water solubility</strong></td>
<td>&gt; 1,000 mg/l</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-</strong></td>
<td>log Pow: -1.41</td>
</tr>
</tbody>
</table>
octanol/water
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

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
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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
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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.

**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 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:
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  
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.  
Shipments by ground under DOT is non-regulated; however it 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:
- IECSC: not determined
- DSL: not determined
- AICS: not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Tulathromycin Formulation

Version 3.5
Revision Date: 04/04/2023
SDS Number: 5297468-00009
Date of last issue: 10/01/2022
Date of first issue: 11/13/2019

NFPA 704:

HEALTH 3

FLAMMABILITY 1

PHYSICAL HAZARD 0

HMIS® IV:

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
Tulathromycin Formulation

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