Oxytetracycline Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Oxytetracycline Formulation

Manufacturer or supplier’s details
Company : MSD
Address : No. 485 Jing Tai Road
          Pu Tuo District - Shanghai - China 200331
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | Aerosol containing a liquefied gas |
| Colour     | blue                              |
| Odour      | solvent-like                      |

Flammable aerosol. Pressurised container: May burst if heated. May cause an allergic skin reaction. Causes serious eye irritation. May cause drowsiness or dizziness. May damage the unborn child. Very toxic to aquatic life with long lasting effects.

GHS Classification
Aerosols : Category 2
Serious eye damage/eye irritation : Category 2A
Skin sensitisation : Category 1
Reproductive toxicity : Category 1A
Specific target organ toxicity - single exposure : Category 3
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
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Hazard pictograms : 

Signal word : Danger

Hazard statements : 
- H223 Flammable aerosol.
- H229 Pressurised container: May burst if heated.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.
- H360D May damage the unborn child.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : 

Prevention:
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P210 Keep away from heat/sparks/open flames/hot surfaces.
  No smoking.
- P211 Do not spray on an open flame or other ignition source.
- P251 Do not pierce or burn, even after use.
- P261 Avoid breathing spray.
- P264 Wash skin thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
- P302 + P352 IF ON SKIN: Wash with plenty of water.
- P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.
- P391 Collect spillage.

Storage:
- P405 Store locked up.
- P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Flammable aerosol. Pressurised container: May burst if heated.

Health hazards
Causes serious eye irritation. May cause an allergic skin reaction. May damage the unborn child. May cause drowsiness or dizziness.

Environmental hazards
Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
May displace oxygen and cause rapid suffocation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butane</td>
<td>106-97-8</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Isobutane</td>
<td>75-28-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Propane</td>
<td>74-98-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</tbody>
</table>

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. Remove 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. Rinse mouth thoroughly with water.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention.

Most important symptoms and effects, both acute and delayed : Gastrointestinal disturbance. May cause an allergic skin reaction.
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5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health. If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.

Hazardous combustion products: Carbon oxides

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Evacuate personnel to safe areas. Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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: Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water
spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling

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

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation. If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Do not get in eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

Keep container tightly closed.

Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the environment.

Do not spray on an open flame or other ignition source.

Avoidance of contact: Oxidizing agents

Storage

Conditions for safe storage: Store locked up.

Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Do not pierce or burn, even after use.

Keep cool. Protect from sunlight.

Materials to avoid: Do not store with the following product types:

Self-reactive substances and mixtures

Organic peroxides

Oxidizing agents

Flammable liquids

Pyrophoric liquids

Pyrophoric solids

Self-heating substances and mixtures
8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Components 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>Butane</td>
<td>106-97-8</td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>PC-TWA</td>
<td>350 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-STEL</td>
<td>700 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Isobutane</td>
<td>75-28-5</td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin sensitisation

| Wipe limit          | 100 µg/100 cm² | Internal |

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>40 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

Personal protective equipment

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>Filter type</th>
<th>Skin and body protection</th>
<th>Hand protection</th>
<th>Remarks</th>
<th>Hygiene measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Self-contained breathing apparatus</td>
<td>Skin should be washed after contact.</td>
<td></td>
<td>Take note that the product is flammable, which may impact the selection of hand protection.</td>
<td>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. Wash contaminated clothing before re-use.</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES
## Oxytetracycline Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Aerosol containing a liquefied gas</td>
</tr>
<tr>
<td><strong>Colour</strong></td>
<td>blue</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>solvent-like</td>
</tr>
<tr>
<td><strong>Odour Threshold</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</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>-80 °C</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Flammable aerosol.</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>9.5 %(V)</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>1.8 %(V)</td>
</tr>
<tr>
<td><strong>Vapour pressure</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative vapour 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>0.92 g/cm³</td>
</tr>
<tr>
<td><strong>Solubility(ies)</strong></td>
<td>Water solubility</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Partition coefficient:</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>n-octanol/water</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
<td>Not explosive</td>
</tr>
<tr>
<td><strong>Oxidizing properties</strong></td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- Flammable aerosol.
  Vapours may form explosive mixture with air.
  If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.
  Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

Butane:
Acute inhalation toxicity: LC50 (Rat): 570000 ppm
  Exposure time: 15 min
  Test atmosphere: gas
  Remarks: Based on data from similar materials

Propan-2-ol:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 25 mg/l
  Exposure time: 6 h
  Test atmosphere: vapour

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Isobutane:
Acute inhalation toxicity: LC50 (Rat): 570000 ppm
  Exposure time: 15 min
  Test atmosphere: gas

Propane:
Acute inhalation toxicity: LC50 (Rat): > 800000 ppm
  Exposure time: 15 min
Test atmosphere: gas

**Oxytetracycline:**

- **Acute oral toxicity**: LD50 (Rat): 4,800 mg/kg
  LD50 (Mouse): 2,240 mg/kg
  Remarks: Evidence of phototoxicity was observed

- **Acute inhalation toxicity**: Remarks: No data available

- **Acute dermal toxicity**: Remarks: No data available

- **Acute toxicity (other routes of administration)**: LD50 (Rat): 4,840 mg/kg
  Application Route: Intramuscular
  LD50 (Mouse): 3,500 mg/kg
  Application Route: Subcutaneous

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

- **Propan-2-ol:**
  - Species: Rabbit
  - Result: No skin irritation

- **Oxytetracycline:**
  - Remarks: No data available

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

**Components:**

- **Propan-2-ol:**
  - Species: Rabbit
  - Result: Irritation to eyes, reversing within 21 days

- **Oxytetracycline:**
  - Remarks: No data available

**Respiratory or skin sensitisation**

- **Skin sensitisation**
  May cause an allergic skin reaction.

- **Respiratory sensitisation**
  Not classified based on available information.
Components:

Propan-2-ol:
- Test Type: Buehler Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative

Oxytetracycline:
- Test Type: Human repeat insult patch test (HRIPT)
- Result: Sensitiser

Germ cell mutagenicity
Not classified based on available information.

Components:

Butane:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative

- Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Rat
  Application Route: Inhalation (gas)
  Method: OECD Test Guideline 474
  Result: negative
  Remarks: Based on data from similar materials

Propan-2-ol:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

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

Isobutane:
- Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
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<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
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</table>

<table>
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<tbody>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: inhalation (gas)</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 474</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Propane:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
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<tr>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: inhalation (gas)</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 474</td>
</tr>
<tr>
<td>Result: negative</td>
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<tr>
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</table>

Oxytetracycline:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: Microbial mutagenesis assay (Ames test)</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: Mouse Lymphoma</td>
</tr>
<tr>
<td>Metabolic activation: Metabolic activation</td>
</tr>
<tr>
<td>Result: positive</td>
</tr>
<tr>
<td>Test Type: sister chromatid exchange assay</td>
</tr>
<tr>
<td>Test system: Chinese hamster ovary cells</td>
</tr>
<tr>
<td>Result: equivocal</td>
</tr>
<tr>
<td>Test Type: Chromosomal aberration</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: equivocal</td>
</tr>
<tr>
<td>Test Type: in vivo assay</td>
</tr>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>
Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity: Not classified based on available information.

Components:

Propan-2-ol:
- Species: Rat
- Application Route: inhalation (vapour)
- Exposure time: 104 weeks
- Method: OECD Test Guideline 451
- Result: negative

Oxytetracycline:
- Species: Mouse
- Application Route: Oral
- Exposure time: 104 weeks
- Result: negative
- Species: Rat
- Application Route: Oral
- Exposure time: 103 weeks
- Result: equivocal
- Target Organs: Adrenal gland, Pituitary gland
- Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

Reproductive toxicity: May damage the unborn child.

Components:

Butane:
- Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  Species: Rat
  Application Route: inhalation (gas)
  Method: OECD Test Guideline 422
  Result: negative
- Effects on foetal development: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  Species: Rat
  Application Route: inhalation (gas)
  Method: OECD Test Guideline 422
  Result: negative
Propan-2-ol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

Isobutane:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: inhalation (gas)  
Method: OECD Test Guideline 422  
Result: negative

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: inhalation (gas)  
Method: OECD Test Guideline 422  
Result: negative

Propane:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: inhalation (gas)  
Method: OECD Test Guideline 422  
Result: negative

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: inhalation (gas)  
Method: OECD Test Guideline 422  
Result: negative

Oxytetracycline:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 18 mg/kg body weight  
Result: No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight
Result: Postimplantation loss., Skeletal malformations

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 1,500 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
General Toxicity Maternal: LOAEL: 1,325 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 2,100 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 41.5 mg/kg body weight
Result: Postimplantation loss., No foetal abnormalities

Test Type: Embryo-foetal development
Species: Dog
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 20.75 mg/kg body weight
Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - Assessment: Positive evidence of adverse effects on development from human epidemiological studies.

**STOT - single exposure**
May cause drowsiness or dizziness.

**Components:**

**Butane:**
- Assessment: May cause drowsiness or dizziness.
- Remarks: Based on data from similar materials

**Propan-2-ol:**
- Assessment: May cause drowsiness or dizziness.

**Isobutane:**
- Assessment: May cause drowsiness or dizziness.

**Propane:**
- Assessment: May cause drowsiness or dizziness.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Oxytetracycline Formulation

Version 3.0  Revision Date: 09/13/2019  SDS Number: 671604-00010  Date of last issue: 2019/05/21
Date of first issue: 2016/05/12

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Butane:

Species: Rat
NOAEL: >= 9000 ppm
Application Route: inhalation (gas)
Exposure time: 6 Weeks
Method: OECD Test Guideline 422

Propan-2-ol:

Species: Rat
NOAEL: 12.5 mg/l
Application Route: inhalation (vapour)
Exposure time: 104 Weeks

Isobutane:

Species: Rat
NOAEL: >= 9000 ppm
Application Route: inhalation (gas)
Exposure time: 6 Weeks
Method: OECD Test Guideline 422

Propane:

Species: Rat
NOAEL: 7.214 mg/l
Application Route: inhalation (gas)
Exposure time: 6 Weeks
Method: OECD Test Guideline 422

Oxytetracycline:

Species: Rat
LOAEL: 198 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Bone
Remarks: No significant adverse effects were reported

Species: Mouse
LOAEL: 7,990 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Bone
Remarks: No significant adverse effects were reported

Species: Dog
## Oxytetracycline Formulation

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- **NOAEL**: 125 mg/kg
- **LOAEL**: 250 mg/kg
- **Application Route**: Oral
- **Exposure time**: 12 Months
- **Target Organs**: Testis
- **Remarks**: Significant toxicity observed in testing

### Species

- **Rat**
  - **NOAEL**: 40 mg/kg
  - **LOAEL**: 100 mg/kg
  - **Application Route**: Intraperitoneal
  - **Exposure time**: 14 Days
  - **Target Organs**: Kidney

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

**Components:**

**Oxytetracycline:**

- **Ingestion**: Symptoms: Gastrointestinal disturbance, tooth discoloration
  - **Remarks**: May cause birth defects.

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

**Components:**

**Propan-2-ol:**

- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
  - Exposure time: 24 h
- **Toxicity to microorganisms**: EC50 (Pseudomonas putida): > 1,050 mg/l
  - Exposure time: 16 h

**Oxytetracycline:**

- **Toxicity to fish**: LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): 621 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - EC50 (Daphnia magna (Water flea)): 669 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants: EC50 (Anabaena): 0.032 mg/l
Exposure time: 72 h
NOEC (Anabaena): 0.0031 mg/l
Exposure time: 72 h

M-Factor (Acute aquatic toxicity): 10
M-Factor (Chronic aquatic toxicity): 10

Toxicity to microorganisms: EC50: 17.9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
NOEC: 0.2 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Butane:
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

Propan-2-ol:
Biodegradability: Result: rapidly degradable
BOD/COD: BOD: 1.19 (BOD5) COD: 2.23 BOD/COD: 53 %

Isobutane:
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

Propane:
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Butane:
Partition coefficient: n-octanol/water: log Pow: 2.89

Propan-2-ol:
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- **Partition coefficient:** \( \log Pow \) -
  - **Isobutane:** \( \log Pow: 2.8 \)
  - **Propane:** \( \log Pow: 2.36 \)

**Mobility in soil**
No data available

**Other adverse effects**
No data available

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging:
  - Empty containers should be taken to an approved waste handling site for recycling or disposal.
  - Empty containers retain residue and can be dangerous.
  - Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
  - If not otherwise specified: Dispose of as unused product.
  - Please ensure aerosol cans are sprayed completely empty (including propellant)

### 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
- **UN number:** UN 1950
- **Proper shipping name:** AEROSOLS
- **Class:** 2.1
- **Packing group:** Not assigned by regulation
- **Labels:**
- **UN/IATA-DGR**
- **UN/ID No.:** UN 1950
- **Proper shipping name:** Aerosols, flammable
- **Class:** 2.1
- **Packing group:** Not assigned by regulation
- **Labels:** Flammable Gas
- **Packing instruction (cargo aircraft):** 203
- **Packing instruction (passenger aircraft):** 203

**IMDG-Code**
- **UN number:** UN 1950
Oxytetracycline Formulation

Proper shipping name: AEROSOLS (Oxytetracycline)
Class: 2.1
Packing group: Not assigned by regulation
Labels: 2.1
EmS Code: F-D, S-U
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

GB 6944/12268
UN number: UN 1950
Proper shipping name: AEROSOLS
Class: 2.1
Packing group: Not assigned by regulation
Labels: 2.1

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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals
Catalogue of Hazardous Chemicals: Listed

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)

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<tr>
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<tr>
<td>W3</td>
<td>Aerosols</td>
<td>150 t</td>
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The components of this product are reported in the following inventories:

AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information
Oxytetracycline Formulation

SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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

Date format:  yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA, ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
GBZ 2.1-2007 / PC-TWA : Permissible concentration - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; No - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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 mate-
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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.

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