1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Oxytetracycline Formulation

Supplier’s company name, address and phone number
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerosols</td>
<td>Category 2</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Skin sensitisation</td>
<td>Category 1</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Category 1A</td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure</td>
<td>Category 3</td>
</tr>
<tr>
<td>Short-term (acute) aquatic hazard</td>
<td>Category 1</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard</td>
<td>Category 1</td>
</tr>
</tbody>
</table>

GHS label elements

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Flammable" /></td>
</tr>
</tbody>
</table>

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, hot surfaces, sparks, open flames and other ignition sources. 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 40 °C/ 104 °F.

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

**Other hazards which do not result in classification**

Important symptoms and outlines of the emergency assumed:

May displace oxygen and cause rapid suffocation.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Butane</td>
</tr>
<tr>
<td></td>
<td>Propan-2-ol</td>
</tr>
<tr>
<td></td>
<td>Isobutane</td>
</tr>
<tr>
<td></td>
<td>Propane</td>
</tr>
<tr>
<td></td>
<td>Oxytetracycline</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butane</td>
<td>106-97-8</td>
<td>&gt;= 20 - &lt; 30</td>
<td>2-4</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-207</td>
</tr>
<tr>
<td>Isobutane</td>
<td>75-28-5</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-4</td>
</tr>
<tr>
<td>Propane</td>
<td>74-98-6</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-3</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>&gt;= 2.5 - &lt; 10</td>
<td>9-271</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.

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: Gastrointestinal disturbance. May cause an allergic skin reaction. Causes serious eye irritation. May cause drowsiness or dizziness. May damage the unborn child.

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.

5. FIREFIGHTING MEASURES

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
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.
Wash contaminated clothing before re-use.

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:
Oxidizing solids
Oxidizing liquids
Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

<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>OEL-M</td>
<td>500 ppm 1,200 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Oxytetracycline Formulation

Version: 4.0  Revision Date: 2020/03/23  SDS Number: 671610-00011  Date of last issue: 2019/09/13  Date of first issue: 2016/05/12

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Target substance</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>

Further information: Skin sensitisation

Wipe limit 100 µg/100 cm² Internal

Biological occupational exposure limits

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: Self-contained breathing apparatus
- Hand protection:
- Remarks: Take note that the product is flammable, which may impact the selection of hand protection.
- Skin and body protection: Skin should be washed after contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Aerosol containing a liquefied gas
Colour: blue
Odour: solvent-like
Odour Threshold: No data available
Melting point/freezing point: No data available
Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): Flammable aerosol.
Flammability (liquids): Not applicable
# SAFETY DATA SHEET

## Oxytetracycline Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>2020/03/23</td>
<td>671610-00011</td>
<td>2019/09/13</td>
<td>2016/05/12</td>
</tr>
</tbody>
</table>

### Upper explosion limit / Upper flammability limit: 9.5 %(V)

### Lower explosion limit / Lower flammability limit: 1.8 %(V)

### Flash point: -80 °C

### Decomposition temperature: No data available

### pH: No data available

### Evaporation rate: No data available

### Auto-ignition temperature: No data available

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

### Solubility(ies):
- Water solubility: No data available

### Partition coefficient: n-octanol/water: No data available

### Vapour pressure: No data available

### Density and / or relative density:
- Relative density: No data available
- Density: 0.92 g/cm³
- Relative vapour density: No data available

### Explosive properties: Not explosive

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

### Particle characteristics:
- Particle size: No data available

## 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.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- 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 exposure): LD50 (Rat): 4,840 mg/kg
SAFETY DATA SHEET

Oxytetracycline Formulation

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---

**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
  - 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: 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
  - Test Type: In vitro mammalian cell gene mutation test
  - 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
  - Result: negative
  - Remarks: Based on data from similar materials
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Remarks: Based on data from similar materials

- 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
## Propane:

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

## Oxytetracycline:

### Genotoxicity in vitro

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbial mutagenesis assay (Ames test)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Mouse Lymphoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metabolic activation: Metabolic activation</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td>sister chromatid exchange assay</td>
<td>equivocal</td>
<td></td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

### Genotoxicity in vivo

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micronucleus test</td>
<td>equivocal</td>
<td></td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity - Assessment</td>
<td>Weight of evidence does not support classification as a germ cell mutagen.</td>
<td></td>
</tr>
</tbody>
</table>

## Carcinogenicity

Not classified based on available information.

## Components:

### Propan-2-ol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>inhalation (vapour)</td>
<td>104 weeks</td>
<td>OECD Test Guideline 451</td>
<td>negative</td>
</tr>
</tbody>
</table>
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)
### 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

### 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**

**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.
SAFETY DATA SHEET

Oxytetracycline Formulation

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.

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)
### Oxytetracycline Formulation

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>104 Weeks</th>
</tr>
</thead>
</table>

#### Isobutane:
- **Species**: Rat
- **NOAEL**: \(\geq 9000\) 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
  - **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:**
- Toxicty to fish: LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l Exposure time: 96 h
- Toxicty to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 24 h
- Toxicty to microorganisms: EC50 (Pseudomonas putida): > 1,050 mg/l Exposure time: 16 h

**Oxytetracycline:**
- Toxicty to fish: LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
- Toxicty 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
- Toxicty 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
- Toxicty 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: 2.23BOD/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:**
Partition coefficient: n-octanol/water: log Pow: 0.05

**Isobutane:**
Partition coefficient: n-octanol/water: log Pow: 2.8

**Propane:**
Partition coefficient: n-octanol/water: log Pow: 2.36

**Mobility in soil**
No data available

**Hazardous to the ozone layer**
Not applicable
Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
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 : 2.1

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
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
Refer to section 15 for specific national regulation.
Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Group 4, Type 1 petroleum, Water insoluble liquid, (200 litre), Hazardous rank II, (Remained chemical in a spray can after degassing falls under this group)

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td>102</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propyl alcohol</td>
<td>494</td>
<td>&gt;=10 - &lt;20</td>
</tr>
<tr>
<td>Butane</td>
<td>482</td>
<td>&gt;=40 - &lt;50</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propyl alcohol</td>
<td>494</td>
</tr>
<tr>
<td>Butane</td>
<td>482</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable
Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Organic Solvents Class 2

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

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
According to MITI Notice No. 139 in 1997, the High Pressure Gas Safety Act isn't applied to this product.

Explosive Control Law
Not applicable

Vessel Safety Law
Gases (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Gases (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

| Bulk transportation | Noxious liquid substance (Category Z) |
| Pack transportation | Classified as marine pollutant |

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Not applicable

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

<table>
<thead>
<tr>
<th>AICS</th>
<th>not determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Oxytetracycline Formulation

Version    Revision Date:    SDS Number:    Date of last issue:    Date of first issue:
4.0        2020/03/23  671610-00011  2019/09/13  2016/05/12


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)
JP OEL ISHL : Japan. Administrative Control Levels

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
JP OEL ISHL / ACL : Administrative Control level
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean
JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LSD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for
safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

JP / EN