SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Oxytetracycline Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone : 908-740-4000
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Aerosols, Category 2 : H223: Flammable aerosol.
Eye irritation, Category 2 : H229: Pressurised container: May burst if heated.
Skin sensitisation, Category 1 : H319: Causes serious eye irritation.
Reproductive toxicity, Category 1A : H317: May cause an allergic skin reaction.
Specific target organ toxicity - single exposure, Category 3 : H360D: May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1 : H336: May cause drowsiness or dizziness.
Long-term (chronic) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
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.
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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P391 Collect spillage.

Storage:
P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.

Hazardous components which must be listed on the label:
- Butane
- Propan-2-ol
- Isobutane
- Oxytetracycline

2.3 Other hazards
May displace oxygen and cause rapid suffocation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butane</td>
<td>106-97-8 203-448-7 601-004-00-0</td>
<td>Flam. Gas 1A; H220 Press. Gas Liquefied gas; H280 STOT SE 3; H336</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0 200-661-7 603-117-00-0</td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Isobutane</td>
<td>75-28-5 200-857-2</td>
<td>Flam. Gas 1A; H220 Press. Gas Liquefied</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxytetracycline Formulation

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: Gastrointestinal disturbance
Oxytetracycline Formulation

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

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
- 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.
6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
**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.

**7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers: 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.

Advice on common storage: Do not store with the following product types:
- Self-reactive substances and mixtures
- Organic peroxides
- Oxidizing agents
- Flammable solids
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Substances and mixtures, which in contact with water, emit flammable gases
- Explosives
- Gases

**7.3 Specific end use(s)**

Specific use(s): No data available

---

**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butane</td>
<td>106-97-8</td>
<td>STEL</td>
<td>750 ppm 1,810 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>600 ppm 1,450 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>400 ppm 999 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm 1,250 mg/m³</td>
<td>GB EH40</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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

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<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Fresh water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2251 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>28 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>160 mg/kg food</td>
</tr>
</tbody>
</table>

### 8.2 Exposure controls

**Personal protective equipment**

**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.

**Respiratory protection**

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

Equipment should conform to BS EN 137

**Filter type**

Self-contained breathing apparatus

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

**Appearance**

Aerosol containing a liquefied gas

**Colour**

blue

**Odour**

solvent-like

**Odour Threshold**

No data available

**pH**

No data available

**Melting point/freezing point**

No data available

**Initial boiling point and boiling range**

No data available
Flash point : -80 °C
Evaporation rate : No data available
Flammability (solid, gas) : Flammable aerosol.
Upper explosion limit / Upper flammability limit : 9.5 %(V)
Lower explosion limit / Lower flammability limit : 1.8 %(V)
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : 0.92 g/cm³

Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition 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.

9.2 Other information
Flammability (liquids) : Not applicable
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
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.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- Inhalation
  - LC50 (Rat): 570000 ppm
  - Exposure time: 15 min
  - Test atmosphere: gas
  - Remarks: Based on data from similar materials
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Butane:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
</tr>
<tr>
<td>LC50 (Rat): 570000 ppm</td>
</tr>
<tr>
<td>Exposure time: 15 min</td>
</tr>
<tr>
<td>Test atmosphere: gas</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Propan-2-ol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
</tr>
<tr>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
</tr>
<tr>
<td>LC50 (Rat): &gt; 25 mg/l</td>
</tr>
<tr>
<td>Exposure time: 6 h</td>
</tr>
<tr>
<td>Test atmosphere: vapour</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
</tr>
<tr>
<td>LD50 (Rabbit): &gt; 5,000 mg/kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Isobutane:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
</tr>
<tr>
<td>LC50 (Rat): 570000 ppm</td>
</tr>
<tr>
<td>Exposure time: 15 min</td>
</tr>
<tr>
<td>Test atmosphere: gas</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Propane:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
</tr>
<tr>
<td>LC50 (Rat): &gt; 800000 ppm</td>
</tr>
<tr>
<td>Exposure time: 15 min</td>
</tr>
<tr>
<td>Test atmosphere: gas</td>
</tr>
</tbody>
</table>
## 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>5.0</td>
<td>23.03.2020</td>
<td>673923-00011</td>
<td>13.09.2019</td>
<td>12.05.2016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
<th>Acute toxicity (other routes of administration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>LD50 (Rat): 4,800 mg/kg</td>
<td>Remarks: Evidence of phototoxicity was observed</td>
<td>Remarks: No data available</td>
<td>Application Route: Intramuscular</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 2,240 mg/kg</td>
<td></td>
<td></td>
<td>LD50 (Mouse): 3,500 mg/kg Application Route: Subcutaneous</td>
</tr>
</tbody>
</table>

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

**Components:**

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

### Oxytetracycline
- Remarks: No data available

**Components:**

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

### Oxytetracycline
- Remarks: No data available

**Components:**

- **Propan-2-ol:**
  - Test Type: Buehler Test

### 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
## Oxytetracycline Formulation

**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)
### Oxytetracycline Formulation

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<tr>
<th>Version</th>
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</tr>
</tbody>
</table>

**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:
- **Genotoxicity in vitro**  
  - **Test Type:** Bacterial reverse mutation assay (AMES)  
  - **Result:** negative  
  - **Remarks:** Based on data from similar materials

#### Oxytetracycline:
- **Genotoxicity in vitro**  
  - **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
- **Genotoxicity in vitro**  
  - **Test Type:** Microbial mutagenesis assay (Ames test)  
  - **Result:** negative
  - **Test Type:** Mouse Lymphoma  
  - **Metabolic activation:** Metabolic activation  
  - **Result:** positive
  - **Test Type:** sister chromatid exchange assay  
  - **Test system:** Chinese hamster ovary cells  
  - **Result:** equivocal
  - **Test Type:** Chromosomal aberration  
  - **Result:** negative
- **Genotoxicity in vivo**  
  - **Test Type:** Micronucleus test  
  - **Species:** Mouse  
  - **Cell type:** Bone marrow  
  - **Application Route:** Oral  
  - **Result:** equivocal
  - **Test Type:** in vivo assay  
  - **Species:** Mouse  
  - **Application Route:** Intraperitoneal injection  
  - **Result:** negative

**Germ cell mutagenicity Assessment**  
Weight of evidence does not support classification as a germ cell mutagen.
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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
Oxytetracycline Formulation

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.

STOT - repeated exposure
Not classified based on available information.
### Repeated dose toxicity

**Components:**

**Butane:**  
- Species: Rat  
- NOAEL: $\geq 9000$ ppm  
- Application Route: inhalation (gas)  
- Exposure time: 6 Weeks  
- Method: OECD Test Guideline 422

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butane</td>
<td>Rat</td>
<td>$\geq 9000$ ppm</td>
<td>inhalation (gas)</td>
<td>6 Weeks</td>
<td>OECD Test Guideline 422</td>
</tr>
</tbody>
</table>

**Propan-2-ol:**  
- Species: Rat  
- NOAEL: 12.5 mg/l  
- Application Route: inhalation (vapour)  
- Exposure time: 104 Weeks

**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.

SECTION 12: Ecological information

12.1 Toxicity

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

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

M-Factor (Chronic aquatic toxicity): 10

12.2 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

12.3 Bioaccumulative potential

Components:

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

- **Propan-2-ol**
Oxytetracycline Formulation

Partition coefficient: n-octanol/water
- **Isobutane:**
  - log Pow: 0.05
- **Propane:**
  - log Pow: 2.8

**12.4 Mobility in soil**
No data available

**12.5 Results of PBT and vPvB assessment**
Not relevant

**12.6 Other adverse effects**
No data available

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**
- **Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
- **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)

**SECTION 14: Transport information**

**14.1 UN number**
- **ADN:** UN 1950
- **ADR:** UN 1950
- **RID:** UN 1950
- **IMDG:** UN 1950
- **IATA:** UN 1950

**14.2 UN proper shipping name**
- **ADN:** AEROSOLS
- **ADR:** AEROSOLS
RID : AEROSOLS
IMDG : AEROSOLS
(Oxytetracycline)
IATA : Aerosols, flammable

14.3 Transport hazard class(es)

ADN : 2
ADR : 2
RID : 2
IMDG : 2.1
IATA : 2.1

14.4 Packing group

ADN
Packing group : Not assigned by regulation
Classification Code : 5F
Labels : 2.1

ADR
Packing group : Not assigned by regulation
Classification Code : 5F
Labels : 2.1
Tunnel restriction code : (D)

RID
Packing group : Not assigned by regulation
Classification Code : 5F
Hazard Identification Number : 23
Labels : 2.1

IMDG
Packing group : Not assigned by regulation
Labels : 2.1

IATA (Cargo)
Packing instruction (cargo aircraft) : 203
Packing instruction (LQ) : Y203
Packing group : Not assigned by regulation
Labels : Flammable Gas

IATA (Passenger)
Packing instruction (passenger aircraft) : 203
Packing instruction (LQ) : Y203
Packing group : Not assigned by regulation
Labels : Flammable Gas

14.5 Environmental hazards

ADN
Environmentally hazardous : yes
Oxytetracycline Formulation

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS: not determined
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxytetracycline Formulation

Version 5.0  Revision Date: 23.03.2020  SDS Number: 673923-00011  Date of last issue: 13.09.2019

DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H220 : Extremely flammable gas.
H225 : Highly flammable liquid and vapour.
H280 : Contains gas under pressure; may explode if heated.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H326 : May cause drowsiness or dizziness.
H360D : May damage the unborn child.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Gas : Flammable gases
Flam. Liq. : Flammable liquids
Press. Gas : Gases under pressure
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT SE : Specific target organ toxicity - single exposure
GB EH40 : UK EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 concentra-
<table>
<thead>
<tr>
<th>Classification of the mixture:</th>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerosol 2</td>
<td>Based on product data or assessment</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 1A</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>


Further information: 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.