SAFETY DATA SHEET

Oxytetracycline Formulation

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
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300
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
Eye irritation, Category 2
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

H223: Flammable aerosol.
H229: Pressurised container: May burst if heated.
H319: Causes serious eye irritation.
H317: May cause an allergic skin reaction.
H360D: May damage the unborn child.
H336: May cause drowsiness or dizziness.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

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.
P270 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>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>203-448-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>601-004-00-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>Flam. Liq.2; H225 Eye Irrit.2; H319 STOT SE3; H336</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>200-661-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>603-117-00-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isobutane</td>
<td>75-28-5</td>
<td>Flam. Gas1A; H220 Press. GasLiquefied gas; H280</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>200-857-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>601-004-00-0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Oxytetracycline Formulation

For explanation of abbreviations see section 16.

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

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disturbance</td>
<td>May cause an allergic skin reaction. Causes serious eye irritation.</td>
</tr>
</tbody>
</table>
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 dyeing or other appropriate containment to keep material from spreading. If dyed 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.
- Do not spray on an open flame or other ignition source.

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 contami-
nated 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

### Occupational Exposure Limits

<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>TWA OEL-RL</td>
<td>600 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.430 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Recommended Limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL</td>
<td>750 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.780 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>STEL OEL-RL</td>
<td>500 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.225 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Absorption through the skin, Recommended Limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA OEL-RL</td>
<td>400 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>960 mg/m³</td>
<td></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>Further information: Skin sensitisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>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>Propan-2-ol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>500 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic</td>
<td>888 mg/kg</td>
</tr>
</tbody>
</table>
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Version 5.0  Revision Date: 23.03.2020  SDS Number: 671617-00011  Date of last issue: 13.09.2019  Date of first issue: 12.05.2016

### 7.2 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.

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.
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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
- 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)
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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:
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

Oxytetracycline:
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.

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
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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: >= 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
  - 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
SAFETY DATA SHEET
Oxytetracycline Formulation

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:
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

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
EmS Code : F-D, S-U

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

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

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

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

AICS : not determined
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.
H336 : 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
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

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 (Canad-
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**Oxytetracycline Formulation**

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**Further information**


**Classification of the mixture:**

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<th>STOT SE 3</th>
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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.

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