SAFETY DATA SHEET

Oxytetracycline Formulation

Version 5.3  Revision Date: 27.08.2021  SDS Number: 671617-00014  Date of last issue: 09.04.2021
Date of first issue: 12.05.2016

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
   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.
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
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butane</td>
<td>106-97-8</td>
<td>203-448-7</td>
<td>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</td>
<td>200-661-7</td>
<td>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>
</tbody>
</table>
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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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

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.

<table>
<thead>
<tr>
<th>Isobutane</th>
<th>75-28-5</th>
<th>Flam. Gas 1A; Press. Gas Liquefied gas; STOT SE 3; H336</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200-857-2</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>601-004-00-0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>200-872-9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>601-003-00-5</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Propane</th>
<th>74-98-6</th>
<th>Flam. Gas 1A; Press. Gas Liquefied gas; STOT SE 3; H336</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200-827-9</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>601-003-00-5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>oxytetracycline</th>
<th>79-57-2</th>
<th>Skin Sens. 1A; Repr. 1A; H360D Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>201-212-8</td>
<td>&gt;= 2,5 - &lt; 10</td>
</tr>
</tbody>
</table>
4.2 Most important symptoms and effects, both acute and delayed

Symptoms: Gastrointestinal disturbance

Risks: May cause an allergic skin reaction. Causes serious eye irritation. May cause drowsiness or dizziness. May damage the unborn child. Gas reduces oxygen available for breathing.

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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

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.
- Avoid breathing spray.
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
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. Contaminated work clothing should not be allowed out of the workplace. 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: 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 1.430 mg/m3</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL</td>
<td>750 ppm 1.780 mg/m3</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>
## Further information: Recommended Limit

<table>
<thead>
<tr>
<th>Substance</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 effects</td>
<td>888 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>89 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>319 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>26 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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

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

## Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hand protection</td>
<td></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.

**Filter type**: Self-contained breathing apparatus
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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

9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

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

Propan-2-ol:
Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 25 mg/l
Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity: LD50 (Rabbit): > 5.000 mg/kg
Isobutane:
Acute inhalation toxicity : LC50 (Rat): 570000 ppm
   Exposure time: 15 min
   Test atmosphere: gas

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

Oxytetracycline:
Acute oral toxicity : LD50 (Rat): 4.800 mg/kg
   LD50 (Mouse): 2.240 mg/kg
   Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration)
   LD50 (Rat): 4.840 mg/kg
   Application Route: Intramuscular
   LD50 (Mouse): 3.500 mg/kg
   Application Route: Subcutaneous

Skin corrosion/irritation
Not classified based on available information.

Components:

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

Oxytetracycline:
Remarks : No data available

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

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

Oxytetracycline:
Remarks : No data available
Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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
Propan-2-ol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
   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

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
**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>5.3</td>
<td>27.08.2021</td>
<td>671617-00014</td>
<td>09.04.2021</td>
<td>12.05.2016</td>
</tr>
</tbody>
</table>

**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.
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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
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>5.3</td>
<td>27.08.2021</td>
<td>671617-00014</td>
<td>09.04.2021</td>
<td>12.05.2016</td>
</tr>
</tbody>
</table>

**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- log Pow: 2.89
octanol/water

**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

**Product:**
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**
Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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).
SELECTION 14: Transport information

14.1 UN number

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 1950</th>
</tr>
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<tbody>
<tr>
<td>ADR</td>
<td>UN 1950</td>
</tr>
<tr>
<td>RID</td>
<td>UN 1950</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 1950</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 1950</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>AEROSOLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>AEROSOLS</td>
</tr>
<tr>
<td>RID</td>
<td>AEROSOLS</td>
</tr>
<tr>
<td>IMDG</td>
<td>AEROSOLS (oxytetracycline)</td>
</tr>
<tr>
<td>IATA</td>
<td>Aerosols, flammable</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>2</th>
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<tbody>
<tr>
<td>ADR</td>
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<td>RID</td>
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<tr>
<td>IMDG</td>
<td>2.1</td>
</tr>
<tr>
<td>IATA</td>
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</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
</tr>
<tr>
<td>Classification Code</td>
</tr>
<tr>
<td>Labels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
</tr>
<tr>
<td>Classification Code</td>
</tr>
<tr>
<td>Labels</td>
</tr>
<tr>
<td>Tunnel restriction code</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
</tr>
<tr>
<td>Classification Code</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
</tr>
<tr>
<td>Labels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IMDG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
</tr>
<tr>
<td>Classification Code</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
</tr>
<tr>
<td>Labels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IATA (Cargo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EmS Code</td>
</tr>
</tbody>
</table>
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.
Oxytetracycline Formulation

<table>
<thead>
<tr>
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<td>671617-00014</td>
<td>12.05.2016</td>
<td>09.04.2021</td>
</tr>
</tbody>
</table>

**Full text of H-Statements**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H220</td>
<td>Extremely flammable gas.</td>
</tr>
<tr>
<td>H225</td>
<td>Highly flammable liquid and vapour.</td>
</tr>
<tr>
<td>H280</td>
<td>Contains gas under pressure; may explode if heated.</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td>H336</td>
<td>May cause drowsiness or dizziness.</td>
</tr>
<tr>
<td>H360D</td>
<td>May damage the unborn child.</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life.</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute</td>
<td>Short-term (acute) aquatic hazard</td>
</tr>
<tr>
<td>Aquatic Chronic</td>
<td>Long-term (chronic) aquatic hazard</td>
</tr>
<tr>
<td>Eye Irrit.</td>
<td>Eye irritation</td>
</tr>
<tr>
<td>Flam. Gas</td>
<td>Flammable gases</td>
</tr>
<tr>
<td>Flam. Liq.</td>
<td>Flammable liquids</td>
</tr>
<tr>
<td>Press. Gas</td>
<td>Gases under pressure</td>
</tr>
<tr>
<td>Repr.</td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td>Skin Sens.</td>
<td>Skin sensitisation</td>
</tr>
<tr>
<td>STOT SE</td>
<td>Specific target organ toxicity - single exposure</td>
</tr>
<tr>
<td>ZA OEL</td>
<td>South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits</td>
</tr>
<tr>
<td>ZA OEL / TWA OEL-RL</td>
<td>Long term occupational exposure limits - recommended limit</td>
</tr>
<tr>
<td>ZA OEL / STEL OEL-RL</td>
<td>Short term occupational exposure limits - recommended limit</td>
</tr>
</tbody>
</table>

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; AIIC - Australian Inventory of Industrial Chemicals; 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 Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCAI - Toxic Substances Control Act (United States); UN - United Nations; UNCLP - United Nations Committee of Experts on the Transport of Dangerous Goods.
Further information

Classification of the mixture:

Classification procedure:
Aerosol 2 H223, H229 Based on product data or assessment
Eye Irrit. 2 H319 Calculation method
Skin Sens. 1 H317 Calculation method
Repr. 1A H360D Calculation method
STOT SE 3 H336 Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 1 H410 Calculation method

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.

ZA / EN