SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

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
               Kilsheean, Clonmel Tipperary, IE
   Telephone : 353-51-601000
   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.
Oxytetracycline Formulation

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.

Ecological information: 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.

Toxicological information: 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.

May displace oxygen and cause rapid suffocation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<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>
</table>
SAFETY DATA SHEET
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Oxytetracycline Formulation

Version 5.3  |  Revision Date: 27.08.2021  |  SDS Number: 673928-00014  |  Date of last issue: 09.04.2021  |  Date of first issue: 12.05.2016

<table>
<thead>
<tr>
<th>Registration number</th>
<th>Description of first aid measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butane</td>
<td>Flam. Gas 1A; H220; Press. Gas Liquified gas; H280 STOT SE 3; H336</td>
</tr>
</tbody>
</table>
| 106-97-8  
203-448-7  
601-004-00-0  |                                     |                |
| Propan-2-ol         | Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336  | = 10 - < 20 |
| 67-63-0  
200-661-7  
603-117-00-0  |                                     |                |
| Isobutane           | Flam. Gas 1A; H220; Press. Gas Liquified gas; H280 STOT SE 3; H336  | = 10 - < 20 |
| 75-28-5  
200-857-2  
601-004-00-0  |                                     |                |
| Propane             | Flam. Gas 1A; H220; Press. Gas Liquified gas; H280 STOT SE 3; H336  | = 10 - < 20 |
| 74-98-6  
200-827-9  
601-003-00-5  |                                     |                |
| oxytetracycline     | Skin Sens. 1A; H317 Repr. 1A; H360D Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10  | = 2.5 - < 10 |
| 79-57-2  
201-212-8  |                                     |                |

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.
- 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

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 prod-: 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
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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</td>
<td>250 ppm 600 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>100 ppm 245 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Propane</td>
<td>74-98-6</td>
<td>TWA</td>
<td>500 ppm 900 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information:
Wipe limit: 100 µg/100 cm² Internal

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></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>

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

<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
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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 NS EN 137

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>Physical state</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>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>Flammability (solid, gas)</td>
<td>Flammable aerosol</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>9,5 % (V)</td>
</tr>
<tr>
<td>Flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
<td>1,8 % (V)</td>
</tr>
<tr>
<td>Flammability limit</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>-80 °C</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>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td></td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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according to Regulation (EC) No. 1907/2006

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Density : 0,92 g/cm³
Relative vapour density : No data available
Particle characteristics
   Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : 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 hazard classes as defined in Regulation (EC) No 1272/2008
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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>Application Route: inhalation (gas)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Method: OECD Test Guideline 474</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Isobutane</td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 473</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Propane</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td>Application Route: inhalation (gas)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: OECD Test Guideline 474</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>
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 hu-
Oxytetracycline Formulation

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:
Oxytetracycline Formulation

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: >= 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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: 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.
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:**
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 Endocrine disrupting properties

**Product:**
Assessment : 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.

12.7 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 or ID number

**ADN** : UN 1950
**ADR** : UN 1950
**RID** : UN 1950
**IMDG** : UN 1950
**IATA** : UN 1950

14.2 UN proper shipping name
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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 (LQ): Not assigned by regulation
  - Labels: Flammable Gas

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

14.5 Environmental hazards
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Date of last issue: 09.04.2021
Date of first issue: 12.05.2016

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 Maritime transport in bulk according to IMO instruments
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

P3a FLAMMABLE AEROSOLS
Quantity 1 Quantity 2
150 t 500 t

E1 ENVIRONMENTAL HAZARDS
100 t 200 t

18 Liquefied extremely flammable gases (including LPG) and natural gas
50 t 200 t

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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a necessary part of their education.

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
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / : Long term exposure limit
TWA

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 - Interna-
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Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
Aerosol 2 H223, H229
Eye Irrit. 2 H319
Skin Sens. 1 H317
Repr. 1A H360D
STOT SE 3 H336
Aquatic Acute 1 H400
Aquatic Chronic 1 H410

Classification procedure:
Based on product data or assessment
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
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.

NO / EN