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
               Walton Manor, Walton
               MK7 7AJ Milton Keynes - United Kingdom
   Telephone : 908-740-4000
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Aerosols, Category 2
   H223: Flammable aerosol.
   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
May displace oxygen and cause rapid suffocation.

**SECTION 3: Composition/information on ingredients**

3.2 Mixtures:

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</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</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Press. Gas Liquefied gas; H280</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3; H336</td>
<td></td>
<td></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</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3; H336</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isobutane</td>
<td>75-28-5</td>
<td></td>
<td></td>
<td>Flam. Gas 1A; H220</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
</tbody>
</table>


SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air. Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Gastrointestinal disturbance
Oxytetracycline Formulation

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

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

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health. If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.

Hazardous combustion products: Carbon oxides

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

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Evacuate personnel to safe areas. Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro-
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 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.
- 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 na-
tional regulations. Do not pierce or burn, even after use. Keep 
cool. Protect from sunlight.

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

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butane</td>
<td>106-97-8</td>
<td>STEL</td>
<td>750 ppm 1,810 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>600 ppm 1,450 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>400 ppm 999 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>500 ppm 1,250 mg/m3</td>
<td>GB EH40</td>
</tr>
<tr>
<td>oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN
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 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**

Hand protection

Remarks : Take note that the product is flammable, which may impact the selection of hand protection.

Skin and body protection : Skin should be washed after contact.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 137

Filter type : Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : Aerosol containing a liquefied gas
Colour : blue
Odour : solvent-like
Odour Threshold : No data available

pH : No data available
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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.
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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
  - **Result:** negative

#### Isobutane:
- **Genotoxicity in vitro**
  - **Test Type:** Chromosome aberration test in vitro
  - **Method:** OECD Test Guideline 473
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:

<table>
<thead>
<tr>
<th>Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
<tr>
<td>Effects on foetal develop-ment</td>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

# Isobutane:

<table>
<thead>
<tr>
<th>Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Inhalation (gas)</td>
<td>negative</td>
</tr>
<tr>
<td>Effects on foetal develop-ment</td>
<td>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Inhalation (gas)</td>
<td>negative</td>
</tr>
</tbody>
</table>

# Propane:

<table>
<thead>
<tr>
<th>Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Inhalation (gas)</td>
<td>negative</td>
</tr>
<tr>
<td>Effects on foetal develop-ment</td>
<td>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Inhalation (gas)</td>
<td>negative</td>
</tr>
</tbody>
</table>

# oxytetracycline:

<table>
<thead>
<tr>
<th>Type</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Fertility</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 18 mg/kg body weight</td>
<td>No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported</td>
</tr>
<tr>
<td>Effects on foetal develop-ment</td>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Oxytetracycline Formulation

Version: 5.1  
Revision Date: 05.10.2020  
SDS Number: 673923-00012  
Date of last issue: 23.03.2020  
Date of first issue: 12.05.2016

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:
Oxytetracycline Formulation

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 1950</td>
</tr>
<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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxytetracycline Formulation

Version: 5.1
Revision Date: 05.10.2020
SDS Number: 673923-00012
Date of last issue: 23.03.2020
Date of first issue: 12.05.2016

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

Oxytetracycline Formulation

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
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
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.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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>5.1</td>
<td>05.10.2020</td>
<td>673923-00012</td>
<td>23.03.2020</td>
<td>12.05.2016</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th>H-Statement</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>H325</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>Description</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>GB EH40</td>
<td>UK. EH40 WEL - Workplace Exposure Limits</td>
</tr>
<tr>
<td>GB EH40 / TWA</td>
<td>Long-term exposure limit (8-hour TWA reference period)</td>
</tr>
<tr>
<td>GB EH40 / STEL</td>
<td>Short-term exposure limit (15-minute reference period)</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 - Interna-
International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture:

<table>
<thead>
<tr>
<th>Aerosol 2</th>
<th>Eye Irrit. 2</th>
<th>Skin Sens. 1</th>
<th>Repr. 1A</th>
<th>STOT SE 3</th>
<th>Aquatic Acute 1</th>
<th>Aquatic Chronic 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>H223, H229</td>
<td>H319</td>
<td>H317</td>
<td>H360D</td>
<td>H336</td>
<td>H400</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

- Based on product data or assessment
- 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.

GB / EN