SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

Oxytetracycline Formulation

Version 2.1  Revision Date: 24.04.2019  SDS Number: 2456469-00004  Date of last issue: 18.10.2018
Date of first issue: 13.02.2018

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
Balikhisar Mah. Koyici Kume Evleri No: 765/A
Cubuk Yolu 2. Km
Akyurt / Ankara / TURKIYE

Telephone: +90 312 840 53 00
Telefax: +90 312 827 18 45
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848
Flammable aerosols, Category 2
Gases under pressure, Liquefied gas
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.
H280: Contains gas under pressure; may explode 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 T.R. SEA No 28848
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

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>
</table>

Hazard pictograms:
- Flammable aerosol
- Contains gas under pressure; may explode if heated
- May cause an allergic skin reaction
- Causes serious eye irritation
- May cause drowsiness or dizziness
- May damage the unborn child
- Very toxic to aquatic life with long lasting effects

Signal word: Danger

Hazard statements:
- H223 Flammable aerosol.
- 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.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
**Prevention:**
- P201 Obtain special instructions before use.
- P261 Avoid breathing spray.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P391 Collect spillage.

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

**Additional Labelling:**
- Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50 °C.
- Do not pierce or burn, even after use.
- Do not spray on a naked flame or any incandescent material.
- Keep away from sources of ignition - No smoking.
- Keep out of the reach of children.

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>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
</table>

2 / 20
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

**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>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>(% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>603-117-00-0</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>201-212-8</td>
<td></td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

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.
Oxytetracycline Formulation

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.

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.
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

Oxytetracycline Formulation

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions
- Evacuate personnel to safe areas.
- Remove all sources of ignition.
- Ventilate the area.
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation
- Use with local exhaust ventilation.
- Use only in an area equipped with explosion-proof exhaust ventilation if advised by assessment of the local exposure potential.
Oxytetracycline Formulation

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Do not get in eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.
- Do not spray on an open flame or other ignition source.

Hygiene measures:
- Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Do not pierce or burn, even after use. Keep cool. Protect from sunlight.

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

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>79-57-2</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td>Skin sensitisation</td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

6 / 20
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

Oxytetracycline Formulation

Version 2.1 Revision Date: 24.04.2019 SDS Number: 2456469-00004 Date of last issue: 18.10.2018 Date of first issue: 13.02.2018

### Derived No Effect Level (DNEL):

<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):

<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>Fresh water sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
<td></td>
</tr>
<tr>
<td>Marine sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
<td></td>
</tr>
<tr>
<td>Soil</td>
<td>28 mg/kg dry weight (d.w.)</td>
<td></td>
</tr>
<tr>
<td>Oral (Secondary Poisoning)</td>
<td>160 mg/kg food</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**: Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

**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>
</tbody>
</table>
SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".

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>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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></td>
</tr>
<tr>
<td>Water solubility</td>
<td>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></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>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.
SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

Oxytetracycline Formulation

Version 2.1
Revision Date: 24.04.2019
SDS Number: 2456469-00004
Date of last issue: 18.10.2018
Date of first issue: 13.02.2018

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:

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

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
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

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>
</table>

**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 Formulation

### Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytetracycline</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cyto genetic assay)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.</td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity

Not classified based on available information.

### Propan-2-ol:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal injection</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Oxytetracycline</th>
<th>Test Type: Microbial mutagenesis assay (Ames test)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

|                       | 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                                    |

<table>
<thead>
<tr>
<th>Oxytetracycline</th>
<th>Test Type: Micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Cell type: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Result: equivocal</td>
</tr>
</tbody>
</table>

|                       | Test Type: in vivo assay                            |
|                       | Species: Mouse                                     |
|                       | Application Route: Intraperitoneal injection        |
|                       | Result: negative                                    |
Oxytetracycline Formulation

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:

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

Oxytetracycline:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: 18 mg/kg body weight
Oxytetracycline Formulation

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:

Propan-2-ol:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
Not classified based on available information.
SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

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>
</table>

Repeated dose toxicity

**Components:**

**Propan-2-ol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>12,5 mg/l</td>
<td>inhalation (vapour)</td>
<td>104 Weeks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Oxytetracycline:**

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>198 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Bone</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Mouse</td>
<td>7,990 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Bone</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Dog</td>
<td>125 mg/kg</td>
<td>Oral</td>
<td>12 Months</td>
<td>Testis</td>
<td>Significant toxicity observed in testing</td>
</tr>
<tr>
<td>Rat</td>
<td>40 mg/kg</td>
<td>Intraperitoneal</td>
<td>14 Days</td>
<td>Kidney</td>
<td></td>
</tr>
</tbody>
</table>

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

**Components:**

**Oxytetracycline:**

Ingestion: Symptoms: Gastrointestinal disturbance
Remarks: May cause birth defects.
Oxytetracycline Formulation

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:

Propan-2-ol:
Biodegradability : Result: rapidly degradable
BOD/COD :
BOD: 1.19 (BOD5)
COD: 2.23
BOD/COD: 53 %

12.3 Bioaccumulative potential

Components:

Propan-2-ol:
Partition coefficient: n-octanol/water : log Pow: 0,05

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Empty containers retain residue and can be dangerous.
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
If not otherwise specified: Dispose of as unused product.
Please ensure aerosol cans are sprayed completely empty (including propellant)

SECTION 14: Transport information

14.1 UN number
ADN : UN 1950
# SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

## 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>
</table>

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

### 14.2 UN proper shipping name

| ADN | AEROSOLS |
| ADR | AEROSOLS |
| RID | AEROSOLS |
| IMDG | AEROSOLS (Oxytetracycline) |
| IATA | Aerosols, flammable |

### 14.3 Transport hazard class(es)

| ADN | 2 |
| ADR | 2 |
| RID | 2 |
| IMDG | 2.1 |
| IATA | 2.1 |

### 14.4 Packing group

| ADN | Packing group : Not assigned by regulation  
Classification Code : 5F  
Labels : 2.1 |
| ADR | Packing group : Not assigned by regulation  
Classification Code : 5F  
Labels : 2.1  
Tunnel restriction code : (D) |
| RID | Packing group : Not assigned by regulation  
Classification Code : 5F  
Hazard Identification Number : 23  
Labels : 2.1 |
| IMDG | Packing group : Not assigned by regulation  
Labels : 2.1  
EmS Code : F-D, S-U |
| IATA (Cargo) | Packing instruction (cargo aircraft) : 203  
Packing instruction (LQ) : Y203 |
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

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>
</table>

Packing group: Not assigned by regulation
Labels: Flammable Gas

IATA (Passenger)
Packing instruction (passenger aircraft): 203
Packing instruction (LQ): Y203
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 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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17): Not applicable

Other regulations:

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

AICS: not determined
DSL: not determined
IECSC: not determined
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

H225 : Highly flammable liquid and vapour.
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

Aquat Acute : Short-term (acute) aquatic hazard
Aquat Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory 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, Evalua-
SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures”.

Oxytetracycline Formulation

Version: 2.1
Revision Date: 24.04.2019
SDS Number: 2456469-00004
Date of last issue: 18.10.2018
Date of first issue: 13.02.2018

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

Classification of the mixture:

Classification procedure:

Flam. Aerosol 2 (H223)
Press. Gas Liquefied gas (H280)
Eye Irrit. 2 (H319)
Skin Sens. 1 (H317)
Repr. 1A (H360D)
STOT SE 3 (H336)
Aquatic Acute 1 (H400)
Aquatic Chronic 1 (H410)

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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.

TR / EN