according to Regulation (EC) No. 1907/2006



# Oxytetracycline Formulation

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

# SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Oxytetracycline Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

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 H223: Flammable aerosol.

H229: Pressurised container: May burst if heated.

Eye irritation, Category 2 H319: Causes serious eye irritation.

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

Reproductive toxicity, Category 1A H360D: May damage the unborn child.

Specific target organ toxicity - single ex-

posure, Category 3

H400: Very toxic to aquatic life.

Short-term (acute) aquatic hazard, Cate-

gory 1

H410: Very toxic to aquatic life with long lasting

H336: May cause drowsiness or dizziness.

Long-term (chronic) aquatic hazard, Cat-

egory 1

effects.

#### 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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 protec-

tion/ face protection.

Response:

P391 Collect spillage.

Storage:

P410 + P412 Protect from sunlight. Do not expose to tem-

peratures 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.

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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

### 3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)
	Registration number		
Butane	106-97-8 203-448-7 601-004-00-0	Flam. Gas 1A; H220 Press. Gas Liquefied gas; H280 STOT SE 3; H336	>= 20 - < 30
Propan-2-ol	67-63-0 200-661-7 603-117-00-0	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	
Isobutane	75-28-5 200-857-2 601-004-00-0	Flam. Gas 1A; H220 Press. Gas Liquefied gas; H280 STOT SE 3; H336	>= 10 - < 20
Propane	74-98-6 200-827-9 601-003-00-5	Flam. Gas 1A; H220 Press. Gas Liquefied gas; H280 STOT SE 3; H336	>= 10 - < 20
oxytetracycline	79-57-2 201-212-8	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

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 ad-

vice 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.

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 01.10.2022

 7.0
 04.04.2023
 673924-00018
 Date of first issue: 12.05.2016

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, 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 : Gas reduces oxygen available for breathing.

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 fire-

fighting

: 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.

according to Regulation (EC) No. 1907/2006



# Oxytetracycline Formulation

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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-

tective 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

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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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 ventila-

tion.

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 as-

sessment

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

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 01.10.2022

 7.0
 04.04.2023
 673924-00018
 Date of first issue: 12.05.2016

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**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Butane	106-97-8	OELV - 15 min (STEL)	1,000 ppm	IE OEL
Propan-2-ol	67-63-0	OELV - 8 hrs (TWA)	200 ppm	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			
		OELV - 15 min (STEL)	400 ppm	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			
Isobutane	75-28-5	OELV - 15 min (STEL)	1,000 ppm	IE OEL
oxytetracycline	79-57-2	TWA	500 μg/m3 (OEB 2)	Internal
	Further information: DSEN			
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Propan-2-ol	Workers	Inhalation	Long-term systemic effects	500 mg/m3
	Workers	Skin contact	Long-term systemic effects	888 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	89 mg/m3
	Consumers	Skin contact	Long-term systemic effects	319 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	26 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Propan-2-ol	Fresh water	140.9 mg/l
	Marine water	140.9 mg/l
	Intermittent use/release	140.9 mg/l
	Sewage treatment plant	2251 mg/l
	Fresh water sediment	552 mg/kg dry weight (d.w.)
	Marine sediment	552 mg/kg dry weight (d.w.)

according to Regulation (EC) No. 1907/2006



# Oxytetracycline Formulation

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

Soil	28 mg/kg dry weight (d.w.)
Oral (Secondary Poisoning)	160 mg/kg food

#### 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 137

Filter type : Self-contained breathing apparatus

### **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Physical state : Aerosol containing a liquefied gas

Colour : blue

Odour : solvent-like
Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : Flammable aerosol.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

9.5 %(V)

Lower explosion limit / Lower :

flammability limit

1.8 %(V)

Flash point : -80 °C

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

according to Regulation (EC) No. 1907/2006



# Oxytetracycline Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 01.10.2022

 7.0
 04.04.2023
 673924-00018
 Date of first issue: 12.05.2016

Partition coefficient: n-

octanol/water

: No data available

Vapour pressure : No data available

Relative density : No data available

Density : 0.92 g/cm<sup>3</sup>

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 : Inhalation

exposure Skin contact

Ingestion

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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.

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

**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

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay)

Species: Rat

Application Route: inhalation (gas) Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

Propan-2-ol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Isobutane:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: inhalation (gas) Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

Propane:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay)

Species: Rat

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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- As-

sessment

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

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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-

mans.

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

#### 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 develop-

ment

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 develop-

ment

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 develop-

ment

Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

according to Regulation (EC) No. 1907/2006



# Oxytetracycline Formulation

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

Species: Rat

Application Route: inhalation (gas) Method: OECD Test Guideline 422

Result: negative

Propane:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: inhalation (gas) Method: OECD Test Guideline 422

Result: negative

Effects on foetal develop-

ment

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 capac-

ity, No significant adverse effects were reported

Effects on foetal develop-

ment

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

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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 - As-

sessment

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

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

Isobutane:

Species : Rat

NOAEL : >= 9000 ppm
Application Route : inhalation (gas)
Exposure time : 6 Weeks

Method : OECD Test Guideline 422

Propane:

Species: RatNOAEL: 7.214 mg/lApplication Route: inhalation (gas)

Exposure time : 6 Weeks

Method : OECD Test Guideline 422

oxytetracycline:

Species: RatLOAEL: 198 mg/kgApplication Route: OralExposure time: 13 WeeksTarget 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:** 

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 01.10.2022

 7.0
 04.04.2023
 673924-00018
 Date of first issue: 12.05.2016

Assessment : The substance/mixture does not contain components consid-

ered 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 tox-

city)

10

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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 : 10

toxicity)

### 12.2 Persistence and degradability

#### **Components:**

**Butane:** 

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1.19 (BOD5)

COD: 2.23 BOD/COD: 53 %

Isobutane:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Propane:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

### 12.3 Bioaccumulative potential

### **Components:**

Butane:

Partition coefficient: n- : log Pow: 2.89

octanol/water

Propan-2-ol:

Partition coefficient: n- : log Pow: 0.05

octanol/water

Isobutane:

Partition coefficient: n- : log Pow: 2.8

octanol/water

Propane:

according to Regulation (EC) No. 1907/2006



# Oxytetracycline Formulation

Version Date of last issue: 01.10.2022 Revision Date: SDS Number: 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

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 consid-

ered 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.

Do not dispose of waste into sewer.

Contaminated packaging Please ensure aerosol cans are sprayed completely empty

(including propellant)

Empty containers should be taken to an approved waste han-

dling 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.

# **SECTION 14: Transport information**

## 14.1 UN number or ID number

ADN UN 1950 ADR UN 1950

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 01.10.2022

 7.0
 04.04.2023
 673924-00018
 Date of first issue: 12.05.2016

 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)

Class Subsidiary risks

ADN : 2 2.1

ADR : 2 2.1

**RID** : 2 2.1

**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 : 203

aircraft)

Packing instruction (LQ) : Y203

Packing group : Not assigned by regulation

Labels : Flammable Gas

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 01.10.2022

 7.0
 04.04.2023
 673924-00018
 Date of first issue: 12.05.2016

IATA (Passenger)

Packing instruction (passen: 203

ger aircraft)

Packing instruction (LQ) : Y203

Packing group : Not assigned by regulation

Labels : Flammable Gas

14.5 Environmental hazards

**ADN** 

Environmentally hazardous : yes

**ADR** 

Environmentally hazardous : yes

**RID** 

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 14.7 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, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 75

If you intend to use this product as tattoo ink, please contact your ven-

dor.

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

Regulation (EC) No 1005/2009 on substances that de- : Not applicable

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EC) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 01.10.2022

 7.0
 04.04.2023
 673924-00018
 Date of first issue: 12.05.2016

Quantity 1 Quantity 2 P3a FLAMMABLE AEROSOLS 150 t 500 t E1 100 t **ENVIRONMENTAL** 200 t **HAZARDS** 18 Liquefied flammable gases 50 t 200 t (including LPG) and natural gas

### 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.

### 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

according to Regulation (EC) No. 1907/2006



# Oxytetracycline Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 01.10.2022

 7.0
 04.04.2023
 673924-00018
 Date of first issue: 12.05.2016

IE OEL : Ireland. List of Chemical Agents and Occupational Exposure

Limit Values - Schedule 1

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

IE OEL / OELV - 15 min : Occupational exposure limit value (15-minute reference peri-

(STEL)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International 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; TECI -Thailand Existing Chemicals 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**

Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification of the mixture:

# e mixture: Classification procedure:

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

according to Regulation (EC) No. 1907/2006



# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 01.10.2022 7.0 04.04.2023 673924-00018 Date of first issue: 12.05.2016

Aquatic Chronic 1 H410 Calculation method

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IE / EN