

# **Oxytetracycline Formulation**

Version Revision Date: SDS Number: Date of last issue: 10/01/2022 4.11 04/04/2023 671616-00018 Date of first issue: 05/12/2016

#### **SECTION 1. IDENTIFICATION**

Product name : Oxytetracycline Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Flammable aerosols : Category 2

Gases under pressure : Liquefied gas

Eye irritation : Category 2A

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Specific target organ toxicity

- single exposure

Category 3

Simple Asphyxiant

### **GHS** label elements

Hazard pictograms :







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.

May displace oxygen and cause rapid suffocation.



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**Precautionary Statements** 

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P210 Keep away from heat, sparks, open flame and hot surfaces. No smoking.

P211 Do not spray on an open flame or other ignition source.

P251 Pressurized container: Do not pierce or burn, even after use.

P261 Avoid breathing spray.

P264 Wash skin thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing, eye protection and face protection.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a doctor if you feel unwell

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 IF exposed or concerned: Get medical attention. P333 + P313 If skin irritation or rash occurs: Get medical attention.

P337 + P313 If eye irritation persists: Get medical attention. P363 Wash contaminated clothing before reuse.

### Storage:

P405 Store locked up.

P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C (122 °F).

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

#### Other hazards

None known.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Butane	106-97-8	>= 20 - < 30
Castor oil	8001-79-4	>= 20 - < 30
Propan-2-ol	67-63-0	>= 10 - < 20
Isobutane	75-28-5	>= 10 - < 20
Propane	74-98-6	>= 10 - < 20



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79-57-2 Oxytetracycline >= 5 - < 10

Actual concentration is withheld as a trade secret

**SECTION 4. 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.

If inhaled If inhaled, remove to fresh air.

> If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

In case of skin contact In case of contact, immediately flush skin with plenty of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of contact, immediately flush eyes with plenty of water In case of eye contact

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

Gastrointestinal disturbance

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.

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).

Notes to physician Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES** 

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Flash back possible over considerable distance. Vapors may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health. If the temperature rises there is danger of the vessels bursting

due to the high vapor pressure.

Hazardous combustion prod: :

ucts

Carbon oxides



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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.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency procedures

Evacuate personnel to safe areas. Remove all sources of ignition.

Ventilate the area.

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

Methods and materials for containment and cleaning up

Non-sparking tools should be used.

Soak up with inert absorbent material.

Suppress (knock down) gases/vapors/mists with a water spray

jet.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked 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.

### **SECTION 7. HANDLING AND STORAGE**

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.



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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.

Conditions for safe storage

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.

Materials to avoid : 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

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Butane	106-97-8	TWA	800 ppm 1,900 mg/m <sup>3</sup>	NIOSH REL
		STEL	EL 1,000 ppm	
Castor oil	8001-79-4	TWA (mist - total)	10 mg/m³	NIOSH REL
		TWA (mist - respirable)	5 mg/m³	NIOSH REL
Propan-2-ol	67-63-0	TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
		ST	500 ppm 1,225 mg/m <sup>3</sup>	NIOSH REL
		TWA	400 ppm 980 mg/m <sup>3</sup>	NIOSH REL
		TWA	400 ppm 980 mg/m³	OSHA Z-1



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Isobutane	75-28-5	TWA	800 ppm 1,900 mg/m <sup>3</sup>	NIOSH REL		
		STEL	1,000 ppm	ACGIH		
Propane	74-98-6	TWA	1,000 ppm 1,800 mg/m³	NIOSH REL		
		TWA	1,000 ppm 1,800 mg/m <sup>3</sup>	OSHA Z-1		
Oxytetracycline	79-57-2	TWA	500 μg/m3 (OEB 2)	Internal		
	Further information: DSEN					
		Wipe limit	mit 100 μg/100 cm <sup>2</sup> Internal			

### **Biological occupational exposure limits**

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

#### Personal protective equipment

Respiratory protection General and local exhaust ventilation is recommended to

> maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are

> unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

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.

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.

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance** Aerosol containing a liquefied gas

Color blue



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Odor : solvent

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point :  $-112 \,^{\circ}\text{F} / -80 \,^{\circ}\text{C}$ 

Evaporation rate : 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)

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

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

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition 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.

Particle size : No data available

### **SECTION 10. STABILITY AND REACTIVITY**



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Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Flammable aerosol.

Vapors 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.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents Hazardous decomposition : No hazardous de

products

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

#### 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

Castor oil:

Acute oral toxicity : LD50 (Rat): > 4,763 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

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: vapor

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Isobutane:

Acute inhalation toxicity : LC50 (Rat): 570000 ppm

Exposure time: 15 min
Test atmosphere: gas



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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:**

Castor oil:

Species : Rabbit

Result : No skin irritation

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

Oxytetracycline:

Remarks : No data available

### Serious eye damage/eye irritation

Causes serious eye irritation.

**Components:** 

Castor oil:

Species : Rabbit

Result : No eye irritation

Propan-2-ol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days



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Oxytetracycline:

Remarks : No data available

### Respiratory or skin sensitization

### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

Not classified based on available information.

### Components:

Castor oil:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Remarks : Based on data from similar materials

Propan-2-ol:

Test Type : Buehler Test Routes of exposure : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Oxytetracycline:

Test Type : Human repeat insult patch test (HRIPT)

Result : Sensitizer

#### 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



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Castor oil:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

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



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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 (vapor)

Exposure time : 104 weeks

Method : OECD Test Guideline 451

Result : negative

Oxytetracycline:

Species : Mouse
Application Route : Oral
Exposure time : 104 weeks



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Result : negative

Species : Rat
Application Route : Oral
Exposure time : 103 weeks
Result : equivocal

Target Organs : Adrenal gland, Pituitary gland

Remarks : The mechanism or mode of action may not be relevant in hu-

mans.

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

### 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 fetal 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

Castor oil:

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

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion

Result: negative

Propan-2-ol:

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

Species: Rat

Application Route: Ingestion



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Result: negative

Effects on fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

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

Result: negative

Propane:

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 fetal development : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

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

Result: negative

Oxytetracycline:

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

Species: Rat

Application Route: Oral

Fertility: NOAEL: 18 mg/kg body weight

Result: No effects on fertility., No effect on reproduction capacity., No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Embryo-fetal toxicity.: LOAEL: 48 mg/kg body weight Result: Postimplantation loss., Skeletal malformations.

Test Type: Embryo-fetal development

Species: Rat



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Application Route: Oral

General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 1,500 mg/kg body weight

Result: No teratogenic effects.

Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development

Species: Mouse

Application Route: Oral

General Toxicity Maternal: LOAEL: 1,325 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 2,100 mg/kg body weight

Result: No teratogenic effects.

Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Intramuscular

Embryo-fetal toxicity.: LOAEL: 41.5 mg/kg body weight Result: Postimplantation loss., No fetal abnormalities.

Test Type: Embryo-fetal development

Species: Dog

Application Route: Intramuscular

Embryo-fetal 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.



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### Repeated dose toxicity

### **Components:**

**Butane:** 

**Species** Rat

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

Method **OECD Test Guideline 422** 

Castor oil:

**Species** Rat

NOAEL > 5,000 mg/kgApplication Route Ingestion Exposure time 13 Weeks

Propan-2-ol:

Species Rat NOAEL 12.5 mg/l

Application Route inhalation (vapor) 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 inhalation (gas) **Application Route** 6 Weeks

Exposure time

Method **OECD Test Guideline 422** 

Oxytetracycline:

**Species** Rat LOAEL 198 mg/kg Application Route Oral Exposure time 13 Weeks **Target Organs** Bone

No significant adverse effects were reported Remarks

**Species** Mouse LOAEL 7,990 mg/kg **Application Route** Oral Exposure time 13 Weeks **Target Organs** Bone

Remarks No significant adverse effects were reported



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Species : Dog

NOAEL : 125 mg/kg LOAEL : 250 mg/kg Application Route : Oral Exposure time : 12 Months Target Organs : Testis

Remarks : Significant toxicity observed in testing

Species : Rat

NOAEL : 40 mg/kg

LOAEL : 100 mg/kg

Application Route : Intraperitoneal

Exposure time : 14 Days

Target Organs : Kidney

### **Aspiration toxicity**

Not classified based on available information.

#### **Experience with human exposure**

### **Components:**

Oxytetracycline:

Ingestion : Symptoms: Gastrointestinal disturbance, tooth discoloration

Remarks: May cause birth defects.

#### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

#### Components:

Castor oil:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h Method: ISO 7346/1

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h



# Oxytetracycline Formulation

Version Revision Date: SDS Number: Date of last issue: 10/01/2022 4.11 04/04/2023 671616-00018 Date of first issue: 05/12/2016

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): 54,000 mg/l

Exposure time: 30 min

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

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

Persistence and degradability

**Components:** 

**Butane:** 

Biodegradability : Result: Readily biodegradable.



# **Oxytetracycline Formulation**

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Remarks: Based on data from similar materials

Castor oil:

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: 2.23BOD/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

**Bioaccumulative potential** 

**Components:** 

**Butane:** 

Partition coefficient: n-

octanol/water

log Pow: 2.89

Castor oil:

Partition coefficient: n-

- - - - - - 1/--- - - -

log Pow: > 4

octanol/water Remarks: Calculation

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

Mobility in soil

No data available

Other adverse effects

No data available



# Oxytetracycline Formulation

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#### **SECTION 13. DISPOSAL CONSIDERATIONS**

Disposal methods

Waste from residues Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Please ensure aerosol cans are sprayed completely empty Contaminated packaging

(including propellant)

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.

#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

**UNRTDG** 

UN 1950 UN number Proper shipping name **AEROSOLS** 

Class 2.1

Packing group Not assigned by regulation

Labels 2.1

**IATA-DGR** 

UN 1950 UN/ID No.

Proper shipping name Aerosols, flammable

Class 2.1

Packing group Not assigned by regulation

Labels Flammable Gas

Packing instruction (cargo

aircraft)

203

Packing instruction (passen-

ger aircraft)

203

**IMDG-Code** 

**UN** number UN 1950 Proper shipping name **AEROSOLS** 

(Oxytetracycline)

Class 2.1

Packing group Not assigned by regulation

Labels 2.1 **EmS Code** F-D, S-U Marine pollutant yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### **Domestic regulation**

**49 CFR** 

UN/ID/NA number UN 1950 Proper shipping name Aerosols



# **Oxytetracycline Formulation**

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Class : 2.1

Packing group : Not assigned by regulation

Labels : FLAMMABLE GAS

ERG Code : 126

Marine pollutant : yes(Oxytetracycline)

#### 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.

#### **SECTION 15. REGULATORY INFORMATION**

#### **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Flammable (gases, aerosols, liquids, or solids)

Gases under pressure

Respiratory or skin sensitization

Reproductive toxicity

Serious eye damage or eye irritation

Simple Asphyxiant

Specific target organ toxicity (single or repeated exposure)

SARA 313 : The following components are subject to reporting levels

established by SARA Title III, Section 313:

Propan-2-ol 67-63-0 >= 10 - < 20 %

### **US State Regulations**

#### Pennsylvania Right To Know

 Butane
 106-97-8

 Castor oil
 8001-79-4

 Propan-2-ol
 67-63-0

 Isobutane
 75-28-5

 Propane
 74-98-6

 Oxytetracycline
 79-57-2

#### California Prop. 65

WARNING: This product can expose you to chemicals including Oxytetracycline, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

#### **California List of Hazardous Substances**

Butane 106-97-8 Propan-2-ol 67-63-0



# **Oxytetracycline Formulation**

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#### **California Permissible Exposure Limits for Chemical Contaminants**

 Butane
 106-97-8

 Propan-2-ol
 67-63-0

 Propane
 74-98-6

### The ingredients of this product are reported in the following inventories:

AICS : not determined

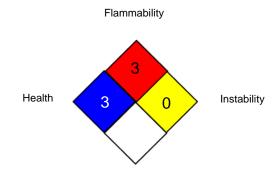
DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

#### **Further information**

#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded

at any time during a workday

OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation,



# **Oxytetracycline Formulation**

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and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Revision Date : 04/04/2023

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.

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