

## **Oxytetracycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0	28.09.2024	9372761-00009	Date of first issue: 27.08.2021

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

1.1	Product identifier Trade name	:	Oxytetracycline Formulation
12	Relevant identified uses of the	2 5	ubstance or mixture and uses advised against
			Veterinary product
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the s	af	ety data sheet
	Company	:	MSD Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom
	Telephone	:	+1-908-740-4000
	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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Aerosols, Category 2

Eye irritation, Category 2 Skin sensitisation, Category 1 Reproductive toxicity, Category 1A Specific target organ toxicity - single exposure, Category 3 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1 H223: Flammable aerosol.
H229: Pressurised container: May burst if heated.
H319: Causes serious eye irritation.
H317: May cause an allergic skin reaction.
H360D: May damage the unborn child.
H336: May cause drowsiness or dizziness.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.



## **Oxytetracycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0	28.09.2024	9372761-00009	Date of first issue: 27.08.2021

#### 2.2 Label elements

# Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :		
Signal word :	Danger	• • •
Hazard statements :	H223 H229 H317 H319 H336 H360D H410	Flammable aerosol. Pressurised container: May burst 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.
Precautionary statements :	Preventior	
	P201 P210	Obtain special instructions before use. 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 P280	Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection.
	Response	
	P391	Collect spillage.
	<b>Storage:</b> P410 + P4 <sup>2</sup>	12 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.

May displace oxygen and cause rapid suffocation.



## **Oxytetracycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0	28.09.2024	9372761-00009	Date of first issue: 27.08.2021

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

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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	>= 10 - < 20
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 advice immediately.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

## **Oxytetracycline Formulation**

Version 7.0	Revision Date: 28.09.2024	SDS Numbe 9372761-00	
		When sy advice.	mptoms persist or in all cases of doubt seek medical
Prote	ction of first-aiders	and use	responders should pay attention to self-protection, the recommended personal protective equipment potential for exposure exists (see section 8).
lf inha	If inhaled		, remove to fresh air. athing, give artificial respiration. ng is difficult, give oxygen. cal attention immediately.
In cas	In case of skin contact		f contact, immediately flush skin with plenty of water. contaminated clothing and shoes. cal attention. thing before reuse. nly clean shoes before reuse.
In cas	se of eye contact	for at lea If easy to	f contact, immediately flush eyes with plenty of water st 15 minutes. do, remove contact lens, if worn. cal attention.
lf swa	If swallowed		ved, DO NOT induce vomiting. cal attention. outh thoroughly with water.
4.2 Most i	mportant symptoms	and effects, bo	th acute and delayed
Symp			estinal disturbance
Risks		Causes s May cau	se an allergic skin reaction. serious eye irritation. se drowsiness or dizziness. lage the unborn child.
		Gas redu	ces oxygen available for breathing.
4.3 Indica	tion of anv immedia	te medical atter	tion and special treatment needed
	ment		nptomatically 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.



## **Oxytetracycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0	28.09.2024	9372761-00009	Date of first issue: 27.08.2021

#### 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.
	Hazardous combustion prod- ucts	:	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).
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#### 6.2 Environmental precautions

Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).
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#### 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 contain- ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
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## **Oxytetracycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0	28.09.2024	9372761-00009	Date of first issue: 27.08.2021
		bent. Local or nationa posal of this ma employed in the mine which reg Sections 13 and	ning materials from spill with suitable absor- al regulations may apply to releases and dis- aterial, as well as those materials and items a cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding 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

		0	
	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 Hygiene measures	:	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. 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,	, inc	luding any incompatibilities
	Requirements for storage	•	Store locked up. Keep tightly closed. Keep in a cool, well-

Requirements for storage areas and containers	:	Store locked up. Keep tightly closed. Keep in a cool, well- ventilated place. Store in accordance with the particular na- tional regulations. Do not pierce or burn, even after use. Keep cool. Protect from sunlight.
Advice on common storage	:	Do not store with the following product types: Self-reactive substances and mixtures Organic peroxides

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

Version 7.0	Revision Date: 28.09.2024	SDS Number: 9372761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
			ds ids ds bstances and mixtures d mixtures, which in contact with water, emit
7 2 6			

#### 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	TWA	600 ppm 1,450 mg/m3	GB EH40	
	Further infor	mation: Capable of ca	ausing cancer and/or heritab	le genetic dam-	
	age.				
		STEL	750 ppm	GB EH40	
			1,810 mg/m3		
	Further infor	information: Capable of causing cancer and/or heritable g			
	age.				
Propan-2-ol	67-63-0	STEL	500 ppm 1,250 mg/m3	GB EH40	
		TWA	400 ppm 999 mg/m3	GB EH40	
oxytetracycline	79-57-2	TWA	500 µg/m3 (OEB 2)	Internal	
	Further infor	mation: DSEN			
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal	

#### Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health ef- fects	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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0	28.09.2024	9372761-00009	Date of first issue: 27.08.2021

#### Predicted No Effect Concentration (PNEC)

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.)
	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 BS EN 137
Filter type	:	Self-contained breathing apparatus

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

#### 9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold		Aerosol containing a liquefied gas blue solvent-like No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available
range Flash point	:	-80 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Flammable aerosol.
Upper explosion limit / Upper flammability limit	:	9.5 %(V)
Lower explosion limit / Lower	:	1.8 %(V)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

Versi 7.0	on	Revision Date: 28.09.2024		S Number: 2761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
f	ilammal	bility limit			
١	Vapour	pressure	:	No data available	9
F	Relative	e vapour density	:	No data available	9
F	Relative	e density	:	No data available	)
[	Density		:	0.92 g/cm <sup>3</sup>	
F C A E	Partitior octanol/ Auto-igr Decomp Viscosit Visco Explosiv	er solubility n coefficient: n- /water nition temperature position temperature	::	No data available No data available No data available No data available No data available Not explosive The substance o	9 9 9
9.2 O	ther in	formation			
F	Flamma	ability (liquids)	:	Not applicable	
F	Particle	size	:	No data available	)

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

<ul> <li>Hazardous reactions</li> <li>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.</li> <li>10.4 Conditions to avoid</li> <li>Heat, flames and sparks.</li> <li>10.5 Incompatible materials Materials to avoid</li> <li>Oxidizing agents</li> </ul>	10.3 Possibility of hazardous reactions				
Conditions to avoid : Heat, flames and sparks. <b>10.5 Incompatible materials</b>	Hazardous reactions	:	Vapours may form explosive mixture with air. If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.		
10.5 Incompatible materials			Heat flames and snarks		
· · · · · · · · · · · · · · · · · · ·		-	neat, names and sparks.		
Materials to avoid : Oxidizing agents	10.5 Incompatible materials				
	Materials to avoid	:	Oxidizing agents		

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0	28.09.2024	9372761-00009	Date of first issue: 27.08.2021

Eye contact

#### 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	:	Inhalation
exposure		Skin contact
		Indestion

#### Acute toxicity

Not classified based on available information.

#### **Components:**

#### Butane:

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	<ul> <li>LD50 (Rat): 4,800 mg/kg</li> <li>LD50 (Mouse): 2,240 mg/kg</li> <li>Remarks: Evidence of phototoxicity was observed</li> </ul>	
Acute inhalation toxicity	: Remarks: No data available	
	40/05	-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Version 7.0	Revision Date: 28.09.2024		S Number: 72761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021			
П							
Acute de	ermal toxicity	:	Remarks: No data	available			
Acute to administ	oxicity (other routes of tration)	:	LD50 (Rat): 4,840 Application Route:				
			LD50 (Mouse): 3,5 Application Route:				
	Skin corrosion/irritation Not classified based on available information.						
Compo	nents:						
Propan	-2-ol:						
Species Result		:	Rabbit No skin irritation				
oxytetra	acycline:						
Remark	S	:	No data available				
	eye damage/eye irri serious eye irritation.	tatio	on				
<u>Compo</u>	nents:						
Propan-			D 11 %				
Species Result		:	Rabbit Irritation to eyes, r	eversing within 21 days			
-	acycline:						
Remark	S	:	No data available				
Respira	tory or skin sensitis	atio	n				
	<b>Skin sensitisation</b> May cause an allergic skin reaction.						
-	Respiratory sensitisation Not classified based on available information.						
<u>Compo</u>	nents:						
Propan	-2-ol:						
Test Typ Exposur Species Method Result	e routes	: : : : : : : : : : : : : : : : : : : :	Buehler Test Skin contact Guinea pig OECD Test Guide negative	line 406			

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Version 7.0	Revision Date: 28.09.2024		OS Number: 72761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
	etracycline:			
	Test Type Result		Human repeat ins Sensitiser	sult patch test (HRIPT)
Germ cell mutagenicity Not classified based on availa		able	information.	
<u>Comp</u>	oonents:			
	Butane: Genotoxicity in vitro		Test Type: Bacte Method: OECD T Result: negative	rial reverse mutation assay (AMES) est Guideline 471
				nosome aberration test in vitro est Guideline 473
Geno	toxicity in vivo	: Test Type: Mammalian erythrocy cytogenetic assay) Species: Rat Application Route: inhalation (ga Method: OECD Test Guideline 4 Result: negative Remarks: Based on data from si		e: inhalation (gas) est Guideline 474
Propa	an-2-ol:			
Geno	Genotoxicity in vitro : Te Re		Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
			Test Type: In vitro Result: negative	o mammalian cell gene mutation test
Geno	toxicity in vivo	:	<ul> <li>Test Type: Mammalian erythrocyte micronucleus test (in cytogenetic assay)</li> <li>Species: Mouse</li> <li>Application Route: Intraperitoneal injection</li> <li>Result: negative</li> </ul>	
Isobu	itane:			
Geno	toxicity in vitro	:	Method: OECD T Result: negative Remarks: Based	nosome aberration test in vitro est Guideline 473 on data from similar materials rial reverse mutation assay (AMES)
			Result: negative	on data from similar materials
Geno	toxicity in vivo	:	Test Type: Mamn cytogenetic assay	nalian erythrocyte micronucleus test (in vivo ⁄)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

ersion )	Revision Date: 28.09.2024	SDS Number: 9372761-0000	
		Method: C Result: ne	n Route: inhalation (gas) ECD Test Guideline 474
Propa	ane:		
Genot	toxicity in vitro	Result: ne	: Bacterial reverse mutation assay (AMES) gative Based on data from similar materials
Genot	toxicity in vivo	cytogeneti Species: F Application Method: C Result: ne	Rat n Route: inhalation (gas) ECD Test Guideline 474
oxyte	tracycline:		
Genotoxicity in vitro		: Test Type Result: ne	: Microbial mutagenesis assay (Ames test) gative
			: Mouse Lymphoma activation: Metabolic activation sitive
			: sister chromatid exchange assay m: Chinese hamster ovary cells uivocal
		Test Type Result: ne	: Chromosomal aberration gative
Genot	toxicity in vivo	Species: N Cell type:	Bone marrow า Route: Oral
		Species: N	n Route: Intraperitoneal injection
Germ sessm	cell mutagenicity- As- nent	: Weight of cell mutag	evidence does not support classification as a germ en.

#### Carcinogenicity

Not classified based on available information.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Version 7.0	Revision Date: 28.09.2024	SDS Number: 9372761-0000	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
Comp	oonents:		
Propa	n-2-ol:		
	ation Route sure time od	: Rat : inhalation ( : 104 weeks : OECD Tes : negative	• •
oxyte	tracycline:		
Specie Applic	es ation Route sure time	: Mouse : Oral : 104 weeks : negative	
Expos Result	ation Route sure time t t Organs		and, Pituitary gland inism or mode of action may not be relevant in hu-
Carcir ment	nogenicity - Assess-	: Weight of e cinogen	evidence does not support classification as a car-
May d	oductive toxicity lamage the unborn child ponents:	ł.	
	s on fertility	reproduction Species: R Application	Route: inhalation (gas) ECD Test Guideline 422
Effects	s on foetal develop-	reproduction Species: R Application	Route: inhalation (gas) ECD Test Guideline 422
Propa	ın-2-ol:		
Effects	s on fertility	Species: R	Route: Ingestion

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



ment       Species: Application Result: no         Isobutane:       Isobutane:         Effects on fertility       : Test Type reproduct Species: Application Method: 0 Result: no         Effects on foetal develop- ment       : Test Type reproduct Species: Application Method: 0 Result: no         Propane:       Effects on fertility       : Test Type reproduct Species: Application Method: 0 Result: no         Effects on fertility       : Test Type reproduct Species: Application Method: 0 Result: no	on Route: Ingestion
Effects on fertility : Test Type reproduct Species: Applicatio Method: 0 Result: ne Effects on foetal develop- ment : Test Type reproduct Species: Applicatio Method: 0 Result: ne Effects on fertility : Test Type reproduct Species: Applicatio Method: 0 Result: ne	
Figure 1       Figure 2       Figure 2 <td< td=""><td></td></td<>	
ment reproduct Species: Application Method: 0 Result: no Propane: Effects on fertility : Test Type reproduct Species: Application Method: 0 Result: no Propane:	on Route: inhalation (gas) OECD Test Guideline 422
Effects on fertility : Test Type reproduct Species: Applicatio Method: 0	on Route: inhalation (gas) OECD Test Guideline 422
Effects on fertility : Test Type reproduct Species: Applicatio Method: 0	
	on Route: inhalation (gas) OECD Test Guideline 422
ment reproduct Species: Application	on Route: inhalation (gas) OECD Test Guideline 422
oxytetracycline:	
Effects on fertility : Test Type Species: Applicatio Fertility: N Result: N	e: Two-generation reproduction toxicity study Rat on Route: Oral NOAEL: 18 mg/kg body weight lo effects on fertility, No effect on reproduction capac- gnificant adverse effects were reported
ment Species: Applicatio Embryo-f	e: Embryo-foetal development Rat on Route: Oral foetal toxicity: LOAEL: 48 mg/kg body weight Postimplantation loss., Skeletal malformations
Test Type	

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

Version 7.0	Revision Date: 28.09.2024		DS Number: 372761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
			Embryo-foetal tox Result: No teratog	Maternal: LOAEL: 1,200 mg/kg body weight kicity: NOAEL: 1,500 mg/kg body weight
			Species: Mouse Application Route General Toxicity I Embryo-foetal tox Result: No teratog	Maternal: LOAEL: 1,325 mg/kg body weight kicity: NOAEL: 2,100 mg/kg body weight
			Species: Rabbit Application Route Embryo-foetal tox	vo-foetal development e: Intramuscular kicity: LOAEL: 41.5 mg/kg body weight antation loss., No foetal abnormalities
			Species: Dog Application Route Embryo-foetal tox	vo-foetal development e: Intramuscular kicity: LOAEL: 20.75 mg/kg body weight and visceral variations, Postimplantation loss.
Repr sessr	oductive toxicity - As- ment	:	Positive evidence human epidemiol	e of adverse effects on development from ogical studies.
May	<b>Γ - single exposure</b> cause drowsiness or diz	zine	ess.	
	ponents:			
Buta Asse Rema	ssment	:		siness or dizziness. om similar materials
-	an-2-ol:			
Asse	ssment	:	May cause drows	siness or dizziness.
	u <b>tane:</b> ssment	:	May cause drows	siness or dizziness.
Prop Asse	<b>ane:</b> ssment	:	May cause drows	iness or dizziness.
CTO.	reported experies			

## STOT - repeated exposure

Not classified based on available information.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Version 7.0	Revision Date: 28.09.2024	SDS Number: 9372761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
Butar	ne:		
Speci NOAE Applic Expos Metho	EL cation Route sure time	: Rat : >= 9000 ppm : inhalation (gas) : 6 Weeks : OECD Test Gu	
Propa	an-2-ol:		
Speci NOAE Applic	es	: Rat : 12.5 mg/l : inhalation (vapo : 104 Weeks	our)
Isobu	itane:		
Speci NOAE Applic Expos Metho	EL cation Route sure time	: Rat : >= 9000 ppm : inhalation (gas) : 6 Weeks : OECD Test Gu	
Propa	ane:		
	EL cation Route sure time	: Rat : 7.214 mg/l : inhalation (gas) : 6 Weeks : OECD Test Gu	
oxyte	etracycline:		
Expos	L cation Route sure time et Organs	: Rat : 198 mg/kg : Oral : 13 Weeks : Bone : No significant a	dverse effects were reported
Expos	EL cation Route sure time et Organs	: Mouse : 7,990 mg/kg : Oral : 13 Weeks : Bone : No significant a	dverse effects were reported
Speci NOAE LOAE Applic	EL	: Dog : 125 mg/kg : 250 mg/kg : Oral	

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

Version 7.0	Revision Date: 28.09.2024		DS Number: 372761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021	
	ure time t Organs rks	:	12 Months Testis Significant toxicity	<i>v</i> observed in testing	
Expos	L		Rat 40 mg/kg 100 mg/kg Intraperitoneal 14 Days Kidney		
Not cla	Aspiration toxicity Not classified based on available information. Experience with human exposure				
-	Components:				
oxyte	tracycline:				
Ingest	ion	:	Symptoms: Gastr Remarks: May ca	ointestinal disturbance, tooth discoloration use birth defects.	
SECTION 12: Ecological information					
12.1 Toxic	ity				
<u>Comp</u>	onents:				
Propa	n-2-ol:				
Toxici	ty to fish	:	LC50 (Pimephale Exposure time: 90	s promelas (fathead minnow)): 9,640 mg/l 5 h	
	ty to daphnia and other c invertebrates	:	EC50 (Daphnia m Exposure time: 24	nagna (Water flea)): > 10,000 mg/l 4 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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Version 7.0	Revision Date: 28.09.2024		DS Number: 372761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
Toxici plants	ity to algae/aquatic	:	EC50 (Anabaena Exposure time: 7	
			NOEC (Anabaen Exposure time: 7	
M-Fac icity)	ctor (Acute aquatic tox-	:	10	
Toxici	ity to microorganisms	:	EC50 : 17.9 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
			NOEC : 0.2 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
M-Fac toxicit	ctor (Chronic aquatic y)	:	10	
12.2 Persi	stence and degradabi	lity		
Comp	oonents:			
Butar	ne:			
Biode	gradability	:	Result: Readily b Remarks: Based	iodegradable. on data from similar materials
Propa	an-2-ol:			
Biode	gradability	:	Result: rapidly de	gradable
BOD/	COD	:	BOD: 1,19 (BOD: COD: 2,23 BOD/COD: 53 %	5)
Isobu	itane:			
Biode	gradability	:	Result: Readily b Remarks: Based	iodegradable. on data from similar materials
Propa	ane:			
Biode	gradability	:	Result: Readily b Remarks: Based	iodegradable. on data from similar materials
12.3 Bioad	ccumulative potential			
<u>Comp</u>	oonents:			
Butar	ne:			
Partiti	ion coefficient: n-	:	log Pow: 2.89	

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Version 7.0	Revision Date: 28.09.2024	SDS Number: 9372761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
octar	nol/water		
Prop	an-2-ol:		
Partit octar	tion coefficient: n- nol/water	: log Pow: 0.0	05
Isobu	utane:		
	tion coefficient: n- nol/water	: log Pow: 2.8	3
Prop	ane:		
	tion coefficient: n- nol/water	: log Pow: 2.3	36
12.4 Mob	ility in soil		
No da	ata available		
12.5 Resu	ults of PBT and vPvB a	ssessment	
Prod	uct:		
	ssment	to be either	nce/mixture contains no components considered persistent, bioaccumulative and toxic (PBT), or ent and very bioaccumulative (vPvB) at levels of ner.
12.6 Othe	er adverse effects		
Prod	uct:		
	crine disrupting poten-	ered to have	nce/mixture does not contain components consid- e endocrine disrupting properties for environment o UK REACH Article 57(f).
SECTION	N 13: Disposal consi	derations	
13.1 Was	te treatment methods		
Prod	uct		n accordance with local regulations.

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0	28.09.2024	9372761-00009	Date of first issue: 27.08.2021

#### **SECTION 14: Transport information**

#### 14.1 UN number

ADN	:	UN 1950	
ADR	:	UN 1950	
RID	:	UN 1950	
IMDG	:	UN 1950	
ΙΑΤΑ	:	UN 1950	
14.2 UN proper shipping name			
ADN	:	AEROSOLS	
ADR	:	AEROSOLS	
RID	:	AEROSOLS	
IMDG	:	AEROSOLS (oxytetracycline)	
ΙΑΤΑ	:	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	
ΙΑΤΑ	:	2.1	
14.4 Packing group			
<b>ADN</b> Packing group Classification Code Labels	:	Not assigned by regu 5F 2.1	lation
<b>ADR</b> Packing group Classification Code Labels Tunnel restriction code	: : :	Not assigned by regu 5F 2.1 (D)	lation
<b>RID</b> Packing group Classification Code Hazard Identification Number Labels	: :	Not assigned by regu 5F 23 2.1	lation
IMDG Packing group	:	Not assigned by regu	lation

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

## **Oxytetracycline Formulation**

Vers 7.0	sion	Revision Date: 28.09.2024		OS Number: 72761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
	Labels EmS C	ode	:	2.1 F-D, S-U	
	IATA ( Packing aircraft	g instruction (cargo	:	203	
	Packin	g instruction (LQ) g group	:	Y203 Not assigned by r Flammable Gas	egulation
	IATA (Passenger) Packing instruction (passen- ger aircraft)		:	203	
	Packin	g instruction (LQ) g group	:	Y203 Not assigned by r Flammable Gas	egulation
14.5	5 Enviro	nmental hazards			
	<b>ADN</b> Enviror	nmentally hazardous	:	yes	
	<b>ADR</b> Enviror	nmentally hazardous	:	yes	
	<b>RID</b> Enviror	nmentally hazardous	:	yes	
	<b>IMDG</b> Marine	pollutant	:	yes	

#### 14.6 Special precautions for user

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

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks

: Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Órganic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation	:	Not applicable



## **Oxytetracycline Formulation**

Version 7.0	Revision Date: 28.09.2024	SDS Number: 9372761-00009	Date of last issue: 0 Date of first issue: 2	
ĞE Infe	nnex XIV) 8 Export and import of haza ormed Consent (PIC) Regu ntrol of Major Accident Ha	ulation		ble
P3		FLAMMABLE AE	Quantity '	1 Quantity 2 500 t
E1		ENVIRONMENT/ HAZARDS	AL 100 t	200 t
18		Liquefied flamma (including LPG) a gas	0	200 t

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

#### 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 H225 H280 H317 H319 H336 H260D	:	Extremely flammable gas. Highly flammable liquid and vapour. Contains gas under pressure; may explode if heated. May cause an allergic skin reaction. Causes serious eye irritation. May cause drowsiness or dizziness.
H360D H400 H410	:	May damage the unborn child. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Oxytetracycline Formulation**

Version Revision Date:	SDS Number:	Date of last issue: 06.07.2024
7.0 28.09.2024	9372761-00009	Date of first issue: 27.08.2021
Aquatic Acute Aquatic Chronic Eye Irrit. Flam. Gas Flam. Liq. Press. Gas Repr. Skin Sens. STOT SE GB EH40 GB EH40 / TWA GB EH40 / STEL	<ul> <li>Eye irritation</li> <li>Flammable gases</li> <li>Flammable liquid</li> <li>Gases under pre</li> <li>Reproductive tox</li> <li>Skin sensitisation</li> <li>Specific target or</li> <li>UK. EH40 WEL -</li> <li>Long-term expose</li> </ul>	nic) aquatic hazard is is is ssure kicity

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; 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

#### Further information

Sources of key data used to compile the Safety Data Sheet

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:**

**Classification procedure:** 

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Version 7.0	Revision Date: 28.09.2024	SDS Number: 9372761-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
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
Aquatic Chronic 1		H410	Calculation method

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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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