SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Oxytetracycline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
9.0	28.09.2024	673928-00022	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 Substance/Mixture : Veterinary product

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 exposure, Category 3	H336: May cause drowsiness or dizziness.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements :
H223 Flammable aerosol.
H229 Pressurised container: May burst if heated.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H360D May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P211 Do not spray on an open flame or other ignition source.
P251 Do not pierce or burn, even after use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P391 Collect spillage.

Storage:

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

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

2.3 Other hazards

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.

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

Gas reduces oxygen available for breathing.

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 : None known.

media

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 products	:	Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Evacuate personnel to safe areas. Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective 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 barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can

be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation. If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Avoid breathing spray. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment. Do not spray on an open flame or other ignition source.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

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

Organic peroxides
Oxidizing agents
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Butane	106-97-8	TWA	250 ppm 600 mg/m3	FOR-2011-12-06-1358
Propan-2-ol	67-63-0	TWA	100 ppm 245 mg/m3	FOR-2011-12-06-1358
Propane	74-98-6	TWA	500 ppm 900 mg/m3	FOR-2011-12-06-1358
oxytetracycline	79-57-2	TWA	500 µg/m3 (OEB 2)	Internal
	Further information: DSEN			
		Wipe limit	100 µg/100 cm²	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.)
	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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS 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
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	0,92 g/cm³
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 exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Butane:

Acute inhalation toxicity : LC50 (Rat): 570000 ppm
Exposure time: 15 min
Test atmosphere: gas
Remarks: Based on data from similar materials

Propan-2-ol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 25 mg/l
Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

Isobutane:

Acute inhalation toxicity : LC50 (Rat): 570000 ppm
Exposure time: 15 min
Test atmosphere: gas

Propane:

Acute inhalation toxicity : LC50 (Rat): > 800000 ppm
Exposure time: 15 min
Test atmosphere: gas

oxytetracycline:

Acute oral toxicity : LD50 (Rat): 4.800 mg/kg

		LD50 (Mouse): 2.240 mg/kg Remarks: Evidence of phototoxicity was observed
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	LD50 (Rat): 4.840 mg/kg Application Route: Intramuscular LD50 (Mouse): 3.500 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Components:

Propan-2-ol:

Species	:	Rabbit
Result	:	No skin irritation

oxytetracycline:

Remarks	:	No data available

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Propan-2-ol:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days

oxytetracycline:

Remarks	:	No data available

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Propan-2-ol:

Test Type	:	Buehler Test
Exposure routes	:	Skin contact

Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

oxytetracycline:

Test Type	:	Human repeat insult patch test (HRIPT)
Result	:	Sensitiser

Germ cell mutagenicity

Not classified based on available information.

Components:

Butane:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials

Propan-2-ol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Isobutane:

Genotoxicity in vitro	:	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 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 Application Route: inhalation (gas) Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials

oxytetracycline:

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Result: negative Test Type: Mouse Lymphoma Metabolic activation: Metabolic activation Result: positive Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: equivocal Test Type: Chromosomal aberration Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: equivocal Test Type: in vivo assay Species: Mouse Application Route: Intraperitoneal injection Result: negative
Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Propan-2-ol:

Species	:	Rat
Application Route	:	inhalation (vapour)
Exposure time	:	104 weeks
Method	:	OECD Test Guideline 451
Result	:	negative

oxytetracycline:

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

Species	:	Rat
Application Route	:	Oral
Exposure time	:	103 weeks
Result	:	equivocal
Target Organs	:	Adrenal gland, Pituitary gland
Remarks	:	The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment	:	Weight of evidence does not support classification as a carcinogen

Reproductive toxicity

May damage the unborn child.

Components:

Butane:

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 422 Result: negative
Effects on foetal development	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 422 Result: negative

Propan-2-ol:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

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 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 foetal development	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 422 Result: negative

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 foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral

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

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 1.200 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 1.500 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
General Toxicity Maternal: LOAEL: 1.325 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 2.100 mg/kg body weight
Result: No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 41,5 mg/kg body weight
Result: Postimplantation loss., No foetal abnormalities

Test Type: Embryo-foetal development
Species: Dog
Application Route: Intramuscular
Embryo-foetal toxicity: LOAEL: 20,75 mg/kg body weight
Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - Assessment	:	Positive evidence of adverse effects on development from human epidemiological studies.

STOT - single exposure

May cause drowsiness or dizziness.

Components:

Butane:

Assessment	:	May cause drowsiness or dizziness.
Remarks	:	Based on data from similar materials

Propan-2-ol:

Assessment	:	May cause drowsiness or dizziness.

Isobutane:

Assessment	:	May cause drowsiness or dizziness.

Propane:

Assessment	:	May cause drowsiness or dizziness.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Butane:

Species	:	Rat
NOAEL	:	>= 9000 ppm
Application Route	:	inhalation (gas)
Exposure time	:	6 Weeks
Method	:	OECD Test Guideline 422

Propan-2-ol:

Species	:	Rat
NOAEL	:	12,5 mg/l
Application Route	:	inhalation (vapour)
Exposure time	:	104 Weeks

Isobutane:

Species	:	Rat
NOAEL	:	>= 9000 ppm
Application Route	:	inhalation (gas)
Exposure time	:	6 Weeks
Method	:	OECD Test Guideline 422

Propane:

Species	:	Rat
NOAEL	:	7,214 mg/l
Application Route	:	inhalation (gas)
Exposure time	:	6 Weeks
Method	:	OECD Test Guideline 422

oxytetracycline:

Species	:	Rat
LOAEL	:	198 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Bone
Remarks	:	No significant adverse effects were reported

Species	:	Mouse
LOAEL	:	7.990 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Bone

Remarks	:	No significant adverse effects were reported

Species	:	Dog
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:

Assessment	:	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.

Experience with human exposure

Components:

oxytetracycline:

Ingestion	:	Symptoms: Gastrointestinal disturbance, tooth discoloration Remarks: May cause birth defects.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Propan-2-ol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 9.640 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10.000 mg/l Exposure time: 24 h

Toxicity to microorganisms	:	EC50 (Pseudomonas putida): > 1.050 mg/l Exposure time: 16 h

oxytetracycline:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 621 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 EC50 (Daphnia magna (Water flea)): 669 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Anabaena): 0,032 mg/l Exposure time: 72 h NOEC (Anabaena): 0,0031 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to microorganisms	:	EC50 : 17,9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC : 0,2 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
M-Factor (Chronic aquatic toxicity)	:	10

12.2 Persistence and degradability

Components:

Butane:

Biodegradability	:	Result: Readily biodegradable. Remarks: Based on data from similar materials

Propan-2-ol:

Biodegradability	:	Result: rapidly degradable
BOD/COD	:	BOD: 1,19 (BOD5) COD: 2,23

BOD/COD: 53 %

Isobutane:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

Propane:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

Butane:

Partition coefficient: n-octanol/water : log Pow: 2,89

Propan-2-ol:

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

Isobutane:

Partition coefficient: n-octanol/water : log Pow: 2,8

Propane:

Partition coefficient: n-octanol/water : log Pow: 2,36

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

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 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.

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 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

14.1 UN number or ID number

ADN	:	UN 1950
ADR	:	UN 1950
RID	:	UN 1950
IMDG	:	UN 1950
IATA	:	UN 1950

14.2 UN proper shipping name

ADN	:	AEROSOLS
ADR	:	AEROSOLS
RID	:	AEROSOLS
IMDG	:	AEROSOLS (oxytetracycline)
IATA	:	Aerosols, flammable

14.3 Transport hazard class(es)

		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 aircraft)	:	203
Packing instruction (LQ)	:	Y203
Packing group	:	Not assigned by regulation
Labels	:	Flammable Gas

IATA (Passenger)

Packing instruction (passenger aircraft)	:	203
Packing instruction (LQ)	:	Y203
Packing group	:	Not assigned by regulation
Labels	:	Flammable Gas

14.5 Environmental hazards

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 vendor.
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)		Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable

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

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

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect

pregnant employees against discomfort and injury as a result of the work situation and the working environment.
Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	:	Long term exposure limit

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:**
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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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.

NO / EN