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



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

1.1 Product identifier

Trade name : Oxytetracycline Formulation

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

Use of the Sub-

stance/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

Reproductive toxicity, Category 1A

Specific target organ toxicity - single ex
H360D: May damage the unborn child.

H336: May cause drowsiness or dizziness.

posure, Category 3

Short-term (acute) aguatic hazard, Cate- H400: Very toxic to aguatic life.

gory 1

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

egory 1

effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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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 tem-

peratures exceeding 50 °C/ 122 °F.

Hazardous components which must be listed on the label:

Butane Propan-2-ol Isobutane oxytetracycline

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

May displace oxygen and cause rapid suffocation.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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
67-63-0 200-661-7 603-117-00-0	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	>= 10 - < 20
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
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
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	>= 2.5 - < 10
	EC-No. Index-No. Registration number 106-97-8 203-448-7 601-004-00-0 67-63-0 200-661-7 603-117-00-0 75-28-5 200-857-2 601-004-00-0 74-98-6 200-827-9 601-003-00-5 79-57-2	EC-No. Index-No. Registration number 106-97-8 203-448-7 601-004-00-0 Flam. Gas 1A; H220 Press. Gas Liquefied gas; H280 STOT SE 3; H336 67-63-0 200-661-7 603-117-00-0 Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 75-28-5 200-857-2 601-004-00-0 Flam. Gas 1A; H220 Press. Gas Liquefied gas; H280 STOT SE 3; H336 74-98-6 200-827-9 601-003-00-5 Flam. Gas 1A; H220 Press. Gas Liquefied gas; H280 STOT SE 3; H336 79-57-2 Skin Sens. 1A; H317 Repr. 1A; H360D Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 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).

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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, 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

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

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

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

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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).

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 absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

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



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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 ventila-

tion.

Advice on safe handling : Do not get on skin or clothing.

Avoid breathing spray. Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

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

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Store locked up. Keep tightly closed. Keep in a cool, wellventilated 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

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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

CAS-No.	Value type (Form	Control parameters	Basis
	of exposure)		
106-97-8	OFLV - 15 min	1 000 ppm	IE OEL
.00 01 0		ι,σσσ ρρ	0
67-63-0	OELV - 8 hrs	200 ppm	IE OEL
	(TWA)	• •	
Further information: Substances which have the capacity to penetrate intact			
skin when they come in contact with it, and be absorbed into the body			
	OELV - 15 min	400 ppm	IE OEL
	(STEL)		
Further information: Substances which have the capacity to penetrate intact			
skin when they come in contact with it, and be absorbed into the body			
75-28-5	OELV - 15 min	1,000 ppm	IE OEL
	(STEL)		
79-57-2	TWA	500 μg/m3 (OEB 2)	Internal
Further information: DSEN			
	Wipe limit	100 μg/100 cm ²	Internal
	106-97-8 67-63-0 Further inform skin when the 75-28-5 79-57-2	of exposure) 106-97-8 OELV - 15 min (STEL) 67-63-0 OELV - 8 hrs (TWA) Further information: Substances w skin when they come in contact wi OELV - 15 min (STEL) Further information: Substances w skin when they come in contact wi 75-28-5 OELV - 15 min (STEL) 79-57-2 TWA Further information: DSEN	of exposure) 106-97-8 OELV - 15 min (STEL) 67-63-0 OELV - 8 hrs (TWA) Further information: Substances which have the capacity to pe skin when they come in contact with it, and be absorbed into the OELV - 15 min (STEL) Further information: Substances which have the capacity to pe skin when they come in contact with it, and be absorbed into the 75-28-5 OELV - 15 min (STEL) 79-57-2 TWA 500 μg/m3 (OEB 2) Further information: DSEN

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

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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 I.S. EN 137

Call and taken the angular and the

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

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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.

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10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

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

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Acute inhalation toxicity Remarks: No data available

Remarks: No data available Acute dermal toxicity

Acute toxicity (other routes of : LD50 (Rat): 4,840 mg/kg

administration)

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

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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

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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

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- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

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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 hu-

mans.

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

Reproductive toxicity

May damage the unborn child.

Components:

Butane:

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

reproduction/developmental toxicity screening test

Species: Rat

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

Result: negative

Effects on foetal develop-

ment

Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

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

Result: negative

Propan-2-ol:

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

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Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Isobutane:

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

reproduction/developmental toxicity screening test

Species: Rat

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

Result: negative

Effects on foetal develop-

ment

Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

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

Result: negative

Propane:

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

reproduction/developmental toxicity screening test

Species: Rat

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

Result: negative

Effects on foetal develop-

ment

Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

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

Result: negative

oxytetracycline:

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

Species: Rat

Application Route: Oral

Fertility: NOAEL: 18 mg/kg body weight

Result: No effects on fertility, No effect on reproduction capac-

ity, No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Embryo-foetal toxicity: LOAEL: 48 mg/kg body weight

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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 - 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.

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



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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 WeeksOECD Test Guideline 422 Method

Propan-2-ol:

Species : Rat NOAEL 12.5 mg/l

Application Route : inhalation (vapour)

Exposure time 104 Weeks

Isobutane:

Species

NOAEL >= 9000 ppm : inhalation (gas) Application Route

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

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

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



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Species Dog

NOAEL 125 mg/kg OAEL 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 Intraperitoneal Application Route 14 Days Exposure time Target Organs Kidney

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

The substance/mixture does not contain components consid-Assessment

> ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

Experience with human exposure

Components:

oxytetracycline:

Ingestion Symptoms: Gastrointestinal disturbance, tooth discoloration

Remarks: May cause birth defects.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 24 h

: EC50 (Pseudomonas putida): > 1,050 mg/l Toxicity to microorganisms

Exposure time: 16 h

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



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II

oxytetracycline:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 110 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 621 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 669 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena): 0.032 mg/l

Exposure time: 72 h

NOEC (Anabaena): 0.0031 mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox- :

icity)

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 %

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



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Isobutane:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Propane:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

Butane:

Partition coefficient: n-

: log Pow: 2.89

octanol/water

Propan-2-ol:

Partition coefficient: n-

: log Pow: 0.05

octanol/water

Partition coefficient: n-

: log Pow: 2.8

octanol/water

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 consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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



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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.

Please ensure aerosol cans are sprayed completely empty Contaminated packaging

(including propellant)

Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN UN 1950 **ADR** UN 1950 RID UN 1950 **IMDG** UN 1950 **IATA** UN 1950

14.2 UN proper shipping name

ADN AEROSOLS ADR AEROSOLS RID **AEROSOLS IMDG AEROSOLS** (oxytetracycline)

Aerosols, flammable

IATA

14.3 Transport hazard class(es)

Class Subsidiary risks **ADN** 2 2.1

2 **ADR** 2.1 RID 2 2.1

IMDG 2.1 **IATA** 2.1

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14.4 Packing group

ADN

Packing group : Not assigned by regulation

Classification Code : 5F Labels : 2.1

ADR

Packing group : Not assigned by regulation

Classification Code : 5F Labels : 2.1 Tunnel restriction code : (D)

RID

Packing group : Not assigned by regulation

Classification Code : 5F Hazard Identification Number : 23 Labels : 2.1

IMDG

Packing group : Not assigned by regulation

Labels : 2.1 EmS Code : F-D, S-U

IATA (Cargo)

Packing instruction (cargo : 203

aircraft)

Packing instruction (LQ) : Y203

Packing group : Not assigned by regulation

Labels : Flammable Gas

IATA (Passenger)

Packing instruction (passen- : 203

ger aircraft)

Packing instruction (LQ) : Y203

Packing group : Not assigned by regulation

Labels : Flammable Gas

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

rid

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments

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



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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. Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

laver

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

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

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

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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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

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min : Occupational exposure limit value (15-minute reference peri-

(STEL) od)

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

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associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data 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

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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

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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.

IE / EN