

## Oxytetracycline Formulation

Version 4.0      Revision Date: 04.04.2023      SDS Number: 673913-00018      Date of last issue: 01.10.2022  
Date of first issue: 12.05.2016

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### SECTION 1. IDENTIFICATION

Product name : Oxytetracycline Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use :  
Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Aerosols : Category 2

Serious eye damage/eye  
irritation : Category 2A

Skin sensitization : 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

#### GHS label elements

Hazard pictograms :



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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.  
P202 Do not handle until all safety precautions have been read and understood.  
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.  
P261 Avoid breathing spray.  
P264 Wash skin thoroughly after handling.  
P271 Use only outdoors or in a well-ventilated area.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
P391 Collect spillage.

**Storage:**

P405 Store locked up.  
P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.

**Disposal:**

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

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**Other hazards which do not result in classification**

May displace oxygen and cause rapid suffocation.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Butane	106-97-8	>= 20 -< 30
Castor oil	8001-79-4	>= 20 -< 30
Propan-2-ol	67-63-0	>= 10 -< 20
Isobutane	75-28-5	>= 10 -< 20
Propane	74-98-6	>= 10 -< 20
Oxytetracycline	79-57-2	>= 5 -< 10

**SECTION 4. FIRST AID MEASURES**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
 If not breathing, give artificial respiration.  
 If breathing is difficult, give oxygen.  
 Get medical attention immediately.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
 Remove contaminated clothing and shoes.  
 Get medical attention.  
 Wash clothing before reuse.  
 Thoroughly clean shoes before reuse.
- In case of 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.
- Most important symptoms and effects, both acute and delayed : Gastrointestinal disturbance  
 Gas reduces oxygen available for breathing.  
 May cause an allergic skin reaction.  
 Causes serious eye irritation.  
 May cause drowsiness or dizziness.  
 May damage the unborn child.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam

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		Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health. If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.
Hazardous combustion products	:	Carbon oxides
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.
Special protective equipment for fire-fighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures	:	Evacuate personnel to safe areas. Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapors/mists with a water spray jet. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.  
 If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust 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.
- Conditions for safe storage : Store locked up.  
 Keep tightly closed.  
 Keep in a cool, well-ventilated place.  
 Store in accordance with the particular national regulations.  
 Do not pierce or burn, even after use.  
 Keep cool. Protect from sunlight.
- Materials to avoid : Do not store with the following product types:  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Oxidizing agents  
 Flammable solids  
 Pyrophoric liquids  
 Pyrophoric solids  
 Self-heating substances and mixtures  
 Substances and mixtures which in contact with water emit flammable gases  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Butane	106-97-8	CMP	800 ppm	AR OEL
		STEL	1.000 ppm	ACGIH

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Castor oil	8001-79-4	CMP (Mist)	10 mg/m <sup>3</sup>	AR OEL
Propan-2-ol	67-63-0	CMP	400 ppm	AR OEL
		CMP - CPT	500 ppm	AR OEL
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
Isobutane	75-28-5	STEL	1.000 ppm	ACGIH
Propane	74-98-6	CMP	2.500 ppm	AR OEL
Oxytetracycline	79-57-2	TWA	500 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

## Biological occupational exposure limits

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

## Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Self-contained breathing apparatus

Hand protection

Remarks : Take note that the product is flammable, which may impact the selection of hand protection.

Skin and body protection : Skin should be washed after contact.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
 When using do not eat, drink or smoke.  
 Contaminated work clothing should not be allowed out of the workplace.  
 Wash contaminated clothing before re-use.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aerosol containing a liquefied gas

Color : blue

Odor : solvent

Odor Threshold : No data available

pH : No data available

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Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	-80 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Flammable aerosol.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	9,5 %(V)
Lower explosion limit / Lower flammability limit	:	1,8 %(V)
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	0,92 g/cm <sup>3</sup>
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle size	:	No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Flammable aerosol. Vapors may form explosive mixture with air. If the temperature rises there is danger of the vessels bursting

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due to the high vapor pressure.  
Can react with strong oxidizing agents.

Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Butane:**

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

Acute oral toxicity	:	LD50 (Rat): > 4.763 mg/kg Method: OECD Test Guideline 401
Acute dermal toxicity	:	LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials

**Propan-2-ol:**

Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 25 mg/l Exposure time: 6 h Test atmosphere: vapor
Acute dermal toxicity	:	LD50 (Rabbit): > 5.000 mg/kg

**Isobutane:**

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

Acute inhalation toxicity	:	LC50 (Rat): > 800000 ppm Exposure time: 15 min Test atmosphere: gas
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Acute oral toxicity : LD50 (Rat): 4.800 mg/kg  
 LD50 (Mouse): 2.240 mg/kg  
 Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 4.840 mg/kg  
 Application Route: Intramuscular  
 LD50 (Mouse): 3.500 mg/kg  
 Application Route: Subcutaneous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Castor oil:**

Species : Rabbit  
 Result : No skin irritation

**Propan-2-ol:**

Species : Rabbit  
 Result : No skin irritation

**Oxytetracycline:**

Remarks : No data available

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****Castor oil:**

Species : Rabbit  
 Result : No eye irritation

**Propan-2-ol:**

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

**Oxytetracycline:**

Remarks : No data available

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**Respiratory or skin sensitization****Skin sensitization**

May cause an allergic skin reaction.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Castor oil:**

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

**Propan-2-ol:**

Test Type	: Buehler Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative

**Oxytetracycline:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Butane:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES)
	Method: OECD Test Guideline 471
	Result: negative
Genotoxicity in vivo	: 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	

**Castor oil:**

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

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Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro  
 Result: negative

Test Type: In vitro sister chromatid exchange assay in mammalian cells  
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Mouse  
 Application Route: Ingestion  
 Result: negative

**Propan-2-ol:**

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

Test Type: In vitro mammalian cell gene mutation test  
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Mouse  
 Application Route: Intraperitoneal injection  
 Result: negative

**Isobutane:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
 Method: OECD Test Guideline 473  
 Result: negative  
 Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
 Result: negative  
 Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Rat  
 Application Route: inhalation (gas)  
 Method: OECD Test Guideline 474  
 Result: negative  
 Remarks: Based on data from similar materials

**Propane:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
 Result: negative  
 Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Rat

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Application Route: inhalation (gas)  
 Method: OECD Test Guideline 474  
 Result: negative  
 Remarks: Based on data from similar materials

**Oxytetracycline:**

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

**Carcinogenicity**

Not classified based on available information.

**Components:****Propan-2-ol:**

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

**Oxytetracycline:**

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

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

**Castor oil:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**Propan-2-ol:**

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

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**Isobutane:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat

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

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

**Propane:**

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

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

**Oxytetracycline:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Oral  
 Fertility: NOAEL: 18 mg/kg body weight  
 Result: No effects on fertility., No effect on reproduction capacity., No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Oral  
 Embryo-fetal toxicity.: LOAEL: 48 mg/kg body weight  
 Result: Postimplantation loss., Skeletal malformations.

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

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

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Remarks: Maternal toxicity observed.

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

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

Reproductive toxicity - 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

**Castor oil:**

Species : Rat

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NOAEL : > 5.000 mg/kg  
 Application Route : Ingestion  
 Exposure time : 13 Weeks

**Propan-2-ol:**

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

**Isobutane:**

Species : Rat  
 NOAEL :  $\geq$  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



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|| Target Organs : Kidney

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Oxytetracycline:**

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

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Castor oil:**

|| Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: ISO 7346/1  
Remarks: Based on data from similar materials

|| Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

|| Toxicity to algae/aquatic plants : NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

|| EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

|| Toxicity to microorganisms : EC10 (Pseudomonas putida): 54.000 mg/l  
Exposure time: 30 min

**Propan-2-ol:**

|| Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9.640 mg/l  
Exposure time: 96 h

|| Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10.000 mg/l  
Exposure time: 24 h

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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

M-Factor (Chronic 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

**Persistence and degradability****Components:****Butane:**

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

**Castor oil:**

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

**Propan-2-ol:**

Biodegradability : Result: rapidly degradable

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BOD/COD : BOD: 1.19 (BOD5)COD: 2.23BOD/COD: 53 %

**Isobutane:**

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

**Propane:**

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

**Bioaccumulative potential****Components:****Butane:**

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

**Castor oil:**

Partition coefficient: n-octanol/water : log Pow: > 4  
 Remarks: Calculation

**Propan-2-ol:**

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

**Isobutane:**

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

**Propane:**

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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
 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

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sources of ignition. They may explode and cause injury and/or death.

If not otherwise specified: Dispose of as unused product.

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### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number	: UN 1950
Proper shipping name	: AEROSOLS
Class	: 2.1
Packing group	: Not assigned by regulation
Labels	: 2.1

##### IATA-DGR

UN/ID No.	: UN 1950
Proper shipping name	: Aerosols, flammable
Class	: 2.1
Packing group	: Not assigned by regulation
Labels	: Flammable Gas
Packing instruction (cargo aircraft)	: 203
Packing instruction (passenger aircraft)	: 203

##### IMDG-Code

UN number	: UN 1950
Proper shipping name	: AEROSOLS (Oxytetracycline)
Class	: 2.1
Packing group	: Not assigned by regulation
Labels	: 2.1
EmS Code	: F-D, S-U
Marine pollutant	: yes

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

Not applicable for product as supplied.

#### 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.

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### SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	: Not applicable
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Control of precursors and essential chemicals for the preparation of drugs.	: Propan-2-ol
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**The ingredients of this product are reported in the following inventories:**

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

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**SECTION 16. OTHER INFORMATION**

Revision Date	:	04.04.2023
Date format	:	dd.mm.yyyy

**Further information**

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
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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 other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
AR BEI	:	Argentina. Biological Exposure Indices
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
AR OEL / CMP	:	TLV (Threshold Limit Value)
AR OEL / CMP - CPT	:	STEL (Short Term Limit Value)

AICC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-

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lative 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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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