

Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

SECTION 1. IDENTIFICATION

Product identifier : Oxytetracycline (10%) Formulation

Other means of identification : ENGEMYCIN (A003308)

COOPERS ENGEMYCIN 100 OXYTETRACYCLINE HYDROCHLORIDE 100MG/ML INJECTION (37256)

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Skin irritation : Category 2

Eye irritation : Category 2A

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms







Signal Word : Danger



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

Hazard Statements : H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

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.

P264 Wash skin thoroughly after handling.

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 protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

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 ad-

vice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)	
Oxytetracycline	79-57-2	Skin Sens., 1A Repr., 1A Aquatic Acute, 1 Aquatic Chronic, 1	>= 10 -< 20	
Ethanolamine	141-43-5	Flam. Liq., 4 Acute Tox. (Oral), 4 Acute Tox. (Inhalation), 4 Acute Tox. (Dermal), 4 Skin Corr., 1B Eye Dam., 1 STOT SE, 3	>= 1 -< 2,5	



Oxytetracycline (10%) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 05.12.2023 28.09.2024 5495945-00011 Date of first issue: 10.03.2020 3.0

		Aquatic Acute, 2 Aquatic Chronic, 3	
Sodium hydroxymethanesul- phinate	149-44-0	Muta., 2 Repr., 2	>= 0,1 -< 1

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.

Get medical attention.

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

for at least 15 minutes while removing 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

Causes skin irritation. May cause an allergic skin reaction.

Causes serious eye irritation.

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).

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-Use extinguishing measures that are appropriate to local cir-



Oxytetracycline (10%) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 05.12.2023 28.09.2024 5495945-00011 Date of first issue: 10.03.2020 3.0

cumstances and the surrounding environment. ods

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

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 Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

See Engineering measures under EXPOSURE Technical measures

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation If sufficient ventilation is unavailable, use with local exhaust

ventilation.

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

Avoid breathing mist or vapors.

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.



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

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

environment.

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.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

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		
Oxytetracycline	79-57-2	TWA	500 μg/m3 (OEB 2)	Internal		
	Further infor	Further information: DSEN				
		Wipe limit	100 μg/100 cm ²	Internal		
Ethanolamine	141-43-5	TWA	3 ppm	ACGIH		
		STEL	6 ppm	ACGIH		

Engineering measures: Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Laboratory operations do not require special containment.

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. Combined particulates and organic vapor type

Filter type

Hand protection

Material : Chemical-resistant gloves



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid, Aqueous solution

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : Not applicable

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature :

No data available



Oxytetracycline (10%) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 05.12.2023 28.09.2024 5495945-00011 Date of first issue: 10.03.2020 3.0

Decomposition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle characteristics

Particle size Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known.

Incompatible materials Oxidizing agents Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

Acute inhalation toxicity Acute toxicity estimate: > 40 mg/l

> Exposure time: 4 h Test atmosphere: vapor Method: Calculation method

Acute toxicity estimate: > 5.000 mg/kg Acute dermal toxicity

Method: Calculation method

Components:

Oxytetracycline:

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

LD50 (Mouse): 2.240 mg/kg



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

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

Ethanolamine:

Acute oral toxicity : LD50 (Rat): 1.089 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 11 mg/l

Exposure time: 4 h
Test atmosphere: vapor
Method: Expert judgment

Remarks: Based on national or regional regulation.

Acute dermal toxicity : LD50 (Rabbit, female): 1.018 mg/kg

Sodium hydroxymethanesulphinate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Causes skin irritation.

Components:

Oxytetracycline:

Remarks : No data available

Ethanolamine:

Species : Rabbit

Result : Corrosive after 3 minutes to 1 hour of exposure

Sodium hydroxymethanesulphinate:

Species : Rat

Result : No skin irritation



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Oxytetracycline:

Remarks : No data available

Ethanolamine:

Species : Rabbit

Result : Irreversible effects on the eye

Sodium hydroxymethanesulphinate:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Oxytetracycline:

Test Type : Human repeat insult patch test (HRIPT)

Result : Sensitizer

Ethanolamine:

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

Sodium hydroxymethanesulphinate:

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

Method : OECD Test Guideline 406

Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Oxytetracycline:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

Result: negative



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

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.

Ethanolamine:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Sodium hydroxymethanesulphinate:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: positive

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



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell

mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:

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:

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



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

Embryo-fetal toxicity.: NOAEL: 1.500 mg/kg body weight

Result: No teratogenic effects. Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development

Species: Mouse Application Route: Oral

General Toxicity Maternal: LOAEL: 1.325 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 2.100 mg/kg body weight

Result: No teratogenic effects. Remarks: Maternal toxicity observed.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Intramuscular

Embryo-fetal toxicity.: LOAEL: 41,5 mg/kg body weight Result: Postimplantation loss., No fetal abnormalities.

Test Type: Embryo-fetal development

Species: Dog

Application Route: Intramuscular

Embryo-fetal toxicity.: LOAEL: 20,75 mg/kg body weight Result: Skeletal and visceral variations ., Postimplantation

loss.

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

Ethanolamine:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Sodium hydroxymethanesulphinate:

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

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 422

Result: negative

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

Result: positive

Reproductive toxicity - As-

sessment

: Some evidence of adverse effects on development, based on

animal experiments.

STOT-single exposure

Not classified based on available information.

Components:

Ethanolamine:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Components:

Ethanolamine:

Assessment : No significant health effects observed in animals at concentra-

tions of 0.2 mg/l/6h/d or less.

Repeated dose toxicity

Components:

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: DogNOAEL: 125 mg/kgLOAEL: 250 mg/kgApplication Route: OralExposure time: 12 MonthsTarget 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



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

Target Organs : Kidney

Ethanolamine:

Species : Rat

NOAEL : > 120 mg/kg
Application Route : Ingestion
Exposure time : > 75 Days

Remarks : Based on data from similar materials

Species : Rat

NOAEL : >= 0.15 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

Sodium hydroxymethanesulphinate:

Species : Rat
NOAEL : 600 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Method : OECD Test Guideline 408

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:

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



Oxytetracycline (10%) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 05.12.2023 28.09.2024 5495945-00011 Date of first issue: 10.03.2020 3.0

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-

M-Factor (Chronic aquatic

toxicity) Toxicity to microorganisms

EC50: 17,9 mg/l

10

10

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

Ethanolamine:

Toxicity to fish LC50 (Cyprinus carpio (Carp)): 349 mg/l

Exposure time: 96 h

Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 65 mg/l

Exposure time: 48 h

Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 2,8

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Orange-red killifish)): 1,24 mg/l

Exposure time: 41 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other:

aquatic invertebrates (Chronic toxicity)

NOEC (Daphnia magna (Water flea)): 0,85 mg/l Exposure time: 21 d

EC10 (Pseudomonas putida): > 1.000 mg/l Toxicity to microorganisms

Exposure time: 30 min

Method: OECD Test Guideline 209

Sodium hydroxymethanesulphinate:

Toxicity to fish LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

aquatic invertebrates Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Danio rerio (zebra fish)): 13,5 mg/l

Exposure time: 35 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

EC10 (Daphnia magna (Water flea)): 8 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : NOEC: 10 mg/l

Exposure time: 4 h

Persistence and degradability

Components:

Ethanolamine:

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 90 % Exposure time: 21 d

Method: OECD Test Guideline 301A

Sodium hydroxymethanesulphinate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 77 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Ethanolamine:

Partition coefficient: n- : log Pow: -2,3

octanol/water Method: OECD Test Guideline 107

Sodium hydroxymethanesulphinate:

Partition coefficient: n- : log Pow: < 0,3

octanol/water

Mobility in soil

No data available



Oxytetracycline (10%) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 05.12.2023 28.09.2024 5495945-00011 Date of first issue: 10.03.2020 3.0

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

(oxytetracycline)

Class 9 Packing group Ш Labels 9 Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

Proper shipping name Environmentally hazardous substance, liquid, n.o.s.

(Oxytetracycline)

9 Class Ш Packing group

Miscellaneous Labels

Packing instruction (cargo

aircraft)

964

Packing instruction (passen-

964

ger aircraft)

Environmentally hazardous yes

IMDG-Code

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Oxytetracycline)

Class 9 Ш Packing group Labels 9 **EmS Code** F-A, S-F Marine pollutant yes

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

Not applicable for product as supplied.

Domestic regulation

ANTT



Oxytetracycline (10%) Formulation

Version Revision Date: SDS Number: Date of last issue: 05.12.2023 3.0 28.09.2024 5495945-00011 Date of first issue: 10.03.2020

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxytetracycline)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal : Not applicable

Police

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety

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

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

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



Oxytetracycline (10%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 05.12.2023

 3.0
 28.09.2024
 5495945-00011
 Date of first issue: 10.03.2020

AIIC - 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, 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; 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.

BR / Z8