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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Oxytetracycline / Diclofenac Liquid Formulation

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Eye irritation, Category 2

Skin sensitisation, Category 1

Reproductive toxicity, Category 1A

H319: Causes serious eye irritation.

H317: May cause an allergic skin reaction.

H360FD: May damage fertility. May damage the

unborn child.

Short-term (acute) aquatic hazard, Category 1

Long-term (chronic) aquatic hazard, Cat-

egory 1

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting

effects.

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

2.2 Label elements

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

Hazard pictograms







Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H360FD May damage fertility. May damage the unborn

child.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical

advice/ attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

oxytetracycline Benzyl alcohol

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		, ,
	Registration number		
2-Pyrrolidone	616-45-5	Eye Irrit. 2; H319	>= 30 - < 50
II	210-483-1	Repr. 1B; H360FD	

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

		specific concentration limit Repr. 1B; H360FD > 3 % Repr. 1B; H360FD > 3 %	
oxytetracycline	79-57-2 201-212-8	Skin Sens. 1A; H317 Repr. 1A; H360D Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——— M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 20 - < 25
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317	>= 1 - < 10
Sodium [2-[(2,6- dichlorophenyl)amino]phenyl]acetate	15307-79-6 239-346-4	Acute Tox. 3; H301 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Gastrointestinal tract, Blood, lym- phatic system, Liv- er, Prostate) Aquatic Chronic 2; H411	>= 0.25 - < 1
Sodium hydroxymethanesulphinate	149-44-0 205-739-4	Muta. 2; H341 Repr. 2; H361d	>= 0.1 - < 1
Substances with a workplace exposur		,	
Magnesium oxide	1309-48-4 215-171-9		>= 1 - < 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.

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause an allergic skin reaction.

Causes serious eye irritation.

May damage fertility. May damage the unborn child.

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

: Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

4/32

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

ucts Nitrogen oxides (NOx)

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 : 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.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

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

certain local or national requirements.

6.4 Reference to other sections

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

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

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.

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

Avoid breathing mist or vapours.

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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

 Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

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

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
oxytetracycline	79-57-2	TWA	500 μg/m3 (OEB 2)	Internal
	Further inform	Further information: DSEN		
		Wipe limit	100 μg/100 cm ²	Internal
Magnesium oxide	1309-48-4	TWA (inhalable dust)	10 mg/m3 (Magnesium)	GB EH40
		TWA (Respirable dust)	4 mg/m3 (Magnesium)	GB EH40
		TWA (Fumes)	10 mg/m3 (Magnesium)	GB EH40
Sodium [2-[(2,6-dichloro-phe-nyl)amino]phenyl]a cetate	15307-79-6	TWA	100 μg/m3 (OEB 2)	Internal
	Further information: Skin			

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
2-Pyrrolidone	Workers	Inhalation	Long-term systemic effects	57.8 mg/m3
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	277 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	17.1 mg/m3
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	167 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5.2 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	33.3 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic	4 mg/kg

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

			effects	bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day
Sodium hy- droxymethanesulphi- nate	Workers	Inhalation	Long-term systemic effects	21 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	140 mg/m3
	Workers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Workers	Skin contact	Acute local effects	0.225 mg/cm2

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
2-Pyrrolidone	Fresh water	0.5 mg/l
	Freshwater - intermittent	0.5 mg/l
	Marine water	0.05 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	0.4205 mg/kg dry
		weight (d.w.)
	Soil	0.0612 mg/kg dry
		weight (d.w.)
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg
	Soil	0.456 mg/kg
Sodium hydroxymethanesulphi- nate	Fresh water	0.056 mg/l
	Marine water	0.006 mg/l
	Freshwater - intermittent	0.056 mg/l
	Sewage treatment plant	1 mg/l
	Fresh water sediment	0.046 mg/kg dry
		weight (d.w.)
	Marine sediment	0.005 mg/kg dry
		weight (d.w.)
	Soil	0.011 mg/kg dry
		weight (d.w.)

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

8.2 Exposure controls

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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : light brown
Odour : No data available
Odour Threshold : No data available

pH : 8.3 - 9.0

(as aqueous solution)

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower : No data available

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

flammability limit

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.05 - 1.18 g/cm³

Solubility(ies)

Water solubility : soluble

Partition coefficient: n- : No data available

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : 47.62 mm2/s

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

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 : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

2-Pyrrolidone:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 401

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

icity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

oxytetracycline:

Acute oral toxicity : LD50 (Rat): 4,800 mg/kg

LD50 (Mouse): 2,240 mg/kg

Remarks: Evidence of phototoxicity was observed

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of :

administration)

LD50 (Rat): 4,840 mg/kg

Application Route: Intramuscular

LD50 (Mouse): 3,500 mg/kg Application Route: Subcutaneous

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9373218-00008 Date of first issue: 27.08.2021 4.0

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

LD50 (Rat): 55 - 240 mg/kg Acute oral toxicity

LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of : LD50 (Rat): 97 - 161 mg/kg

administration)

Application Route: Intravenous

LD50 (Mouse): 92 - 147 mg/kg Application Route: Intravenous

Sodium hydroxymethanesulphinate:

LD50 (Rat): > 2,000 mg/kg Acute oral toxicity

Method: OECD Test Guideline 423

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

icity

LD50 (Rat): > 2,000 mg/kg Acute dermal toxicity

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Magnesium oxide:

Acute oral toxicity LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

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

Remarks: Based on data from similar materials

Acute inhalation toxicity LC50 (Rat): > 2.1 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

Components:

2-Pyrrolidone:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

oxytetracycline:

Remarks : No data available

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result : irritating

Sodium hydroxymethanesulphinate:

Species : Rat

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-Pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

oxytetracycline:

Remarks : No data available

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Result : Mild eye irritation

Sodium hydroxymethanesulphinate:

Species : Rabbit

Method : OECD Test Guideline 405

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

Result : No eye irritation

Magnesium oxide:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Species . Wouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

oxytetracycline:

Test Type : Human repeat insult patch test (HRIPT)

Result : Sensitiser

Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Species : Humans Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Sodium hydroxymethanesulphinate:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Magnesium oxide:

Test Type : Maximisation Test

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

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

Remarks: Based on data from similar materials

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: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: negative

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

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

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.

Benzyl alcohol:

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

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

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

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: CHO 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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Germ cell mutagenicity- As-

sessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

Magnesium oxide:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

2-Pyrrolidone:

Species : Mouse
Application Route : Ingestion
Exposure time : 18 month(s)
Result : negative

Remarks : Based on data from similar materials

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

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

Result : negative

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Magnesium oxide:

Species : Mouse
Application Route : Ingestion
Exposure time : 96 weeks
Result : negative

Remarks : Based on data from similar materials

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

2-Pyrrolidone:

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

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse

effects on development, based on animal experiments.

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

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

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

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 1,200 mg/kg body weight Embryo-foetal toxicity: NOAEL: 1,500 mg/kg body weight

Result: No teratogenic effects Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development

Species: Mouse Application Route: Oral

General Toxicity Maternal: LOAEL: 1,325 mg/kg body weight Embryo-foetal toxicity: NOAEL: 2,100 mg/kg body weight

Result: No teratogenic effects Remarks: Maternal toxicity observed.

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Intramuscular

Embryo-foetal toxicity: LOAEL: 41.5 mg/kg body weight Result: Postimplantation loss., No foetal abnormalities

Test Type: Embryo-foetal development

Species: Dog

Application Route: Intramuscular

Embryo-foetal toxicity: LOAEL: 20.75 mg/kg body weight Result: Skeletal and visceral variations, Postimplantation loss.

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

Effects on fertility : Test Type: Fertility

Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: 4 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 5 mg/kg body weight Result: Embryo-foetal toxicity, No teratogenic effects

Reproductive toxicity - As-

sessment

: Suspected of damaging the unborn child.

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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

Reproductive toxicity - As-

sessment

: Some evidence of adverse effects on development, based on

animal experiments.

Magnesium oxide:

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

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

2-Pyrrolidone:

Species : Rat

NOAEL : 207 mg/kg

Application Route : Ingestion

Exposure time : 3 Months

Method : OECD Test Guideline 408

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

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9373218-00008 Date of first issue: 27.08.2021 4.0

Species Rat NOAEL 40 mg/kg LOAEL 100 mg/kg : Intraperitoneal : 14 Days Application Route Exposure time Target Organs : Kidney

Benzyl alcohol:

Species Rat NOAEL

1.072 mg/l
inhalation (dust/mist/fume)
28 Days NUAEL
Application Route

Exposure time

Method : OECD Test Guideline 412

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Species Rat

LOAEL 0.25 mg/kg

Application Route Oral Exposure time 98 w

Target Organs Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species Dog LOAEL 1 mg/kg Application Route : Oral Exposure time 12 w Target Organs : Blood

Species Baboon NOAEL 0.5 mg/kg LOAEL : 5 mg/kg Application Route : Oral Exposure time

52 wGastrointestinal tract, Blood Target Organs Symptoms : constipation, Diarrhoea

Sodium hydroxymethanesulphinate:

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

Method : OECD Test Guideline 408

Magnesium oxide:

Species Rat

>= 1,000 mg/kgNOAEL Application Route : Ingestion

Exposure time 28 Davs

Method **OECD Test Guideline 407**

Remarks Based on data from similar materials

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

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.

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Ingestion : Symptoms: Abdominal pain, Diarrhoea, constipation, heart-

burn, Ulceration, Dizziness, Headache, Breathing difficulties,

Rash

SECTION 12: Ecological information

12.1 Toxicity

Components:

2-Pyrrolidone:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 500 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50 : > 1,000 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

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

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

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

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 51 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 80.1 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2

mq/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.32 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aguatic invertebrates (Chron-

ic toxicity)

NOEC: 10 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Sodium hydroxymethanesulphinate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

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 microorganisms : NOEC : 10 mg/l

Exposure time: 4 h

Toxicity to fish (Chronic tox-

icity)

: NOEC: 13.5 mg/l Exposure time: 35 d

> Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9373218-00008 Date of first issue: 27.08.2021 4.0

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

EC10: 8 mg/l

Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Magnesium oxide:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

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

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

: 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 EC50 : > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

2-Pyrrolidone:

Biodegradability Result: Readily biodegradable.

Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

Sodium hydroxymethanesulphinate:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 77 % Exposure time: 28 d

Method: OECD Test Guideline 301B

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

12.3 Bioaccumulative potential

Components:

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0.71

octanol/water Method: OECD Test Guideline 107

Benzyl alcohol:

Partition coefficient: n- : log Pow: 1.05

octanol/water

Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Partition coefficient: n- : log Pow: 4.51

octanol/water

Sodium hydroxymethanesulphinate:

Partition coefficient: n- : log Pow: < 0.3

octanol/water

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 Other adverse effects

Product:

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

SECTION 14: Transport information

14.1 UN number

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxytetracycline)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxytetracycline)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxytetracycline)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxytetracycline)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(oxytetracycline)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III Classification Code : M6

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

Hazard Identification Number : 90 Labels : 9 Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

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

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

Remarks : Not applicable for product as supplied.

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



Oxytetracycline / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9373218-00008 Date of first issue: 27.08.2021

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the fol-

lowing entries should be considered:

Number on list 3

UK REACH List of restrictions (Annex 17)

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

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone : Not applicable

layer

UK REACH List of substances subject to authorisation

(Annex XIV)

GB Export and import of hazardous chemicals - Prior

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

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

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

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



Oxytetracycline / Diclofenac Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9373218-00008
 Date of first issue: 27.08.2021

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

H301 : Toxic if swallowed. H302 : Harmful if swallowed. H315 : Causes skin irritation.

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

H341 : Suspected of causing genetic defects.

H360D : May damage the unborn child.

H360FD : May damage fertility. May damage the unborn child.

H361d : Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Muta. : Germ cell mutagenicity
Repr. : Reproductive toxicity
Skip Irrit

Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International

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



Oxytetracycline / Diclofenac Liquid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 28.09.2024 Date of first issue: 27.08.2021 4.0 9373218-00008

tional Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to : compile the Safety Data Sheet

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

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

Classification of the mixture: Classification procedure:

Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	Calculation method
Repr. 1A	H360FD	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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

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