

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

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

#### 1.1 Product identifier

Trade name : Oxytetracycline / Diclofenac Formulation

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

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1A	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)


# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

- 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.  
H373 May cause damage to organs through prolonged or repeated exposure.  
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  
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate

### 2.3 Other hazards

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

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration
---------------	---------	----------------	---------------

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

	EC-No. Index-No. Registration number		(% w/w)
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD  specific concentra- tion limit Repr. 1B; H360FD > 3 %	>= 50 - < 70
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
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	>= 1 - < 2,5
Sodium hydroxymethanesulphinate	6035-47-8	Muta. 2; H341 Repr. 2; H361d	>= 0,1 - < 1

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 advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

---

- 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.  
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.  
May cause damage to organs through prolonged or repeated exposure.

### 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 (CO<sub>2</sub>)  
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 products : Carbon oxides  
Chlorine compounds  
Nitrogen oxides (NO<sub>x</sub>)  
Sodium oxides

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

---

### 5.3 Advice for firefighters

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

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

- Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : 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 absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

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

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe 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 assessment  
Keep container tightly closed.  
Do not eat, drink or smoke when using this product.  
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

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
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
Propylene glycol	57-55-6	TWA	25 ppm	FOR-2011-

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

Magnesium oxide	1309-48-4	TWA (Dust)	79 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>	12-06-1358 FOR-2011-12-06-1358
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: Skin				

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
2-Pyrrolidone	Workers	Inhalation	Long-term systemic effects	57,8 mg/m <sup>3</sup>
	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/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	167 mg/kg bw/day
Propylene glycol	Workers	Inhalation	Long-term systemic effects	5,2 mg/kg bw/day
	Workers	Inhalation	Acute systemic effects	33,3 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	168 mg/m <sup>3</sup>
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

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.)
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57,2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

### 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to NS 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

- Physical state : liquid
- Colour : brown, Greenish yellow
- Odour : characteristic
- Odour Threshold : No data available
- Melting point/freezing point : -33 °C
- Initial boiling point and boiling range : 100,5 °C
- Flammability (solid, gas) : Not applicable
- Flammability (liquids) : No data available



# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

---

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

### Viscosity

Viscosity, dynamic : 50,3 - 50,7 mPa.s (25 °C)

Viscosity, kinematic : No data available

### Solubility(ies)

Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : 1,15 - 1,19 (25 °C)

Density : No data available

Relative vapour density : No data available

### Particle characteristics

Particle size : Not applicable

## 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

### 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

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

### SECTION 11: Toxicological information

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

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

#### Acute toxicity

Not classified based on available information.

#### **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 toxicity

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:**

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

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

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

Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg  
LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 97 - 161 mg/kg  
Application Route: Intravenous  
LD50 (Mouse): 92 - 147 mg/kg  
Application Route: Intravenous

### **Sodium hydroxymethanesulphinat:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials  
Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **2-Pyrrolidone:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

#### **oxytetracycline:**

Remarks : No data available

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

Result : irritating

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

### **Sodium hydroxymethanesulphinate:**

Species : Rat  
Result : No skin irritation  
Remarks : Based on data from similar materials

### **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

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

Result : Mild eye irritation

### **Sodium hydroxymethanesulphinate:**

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  
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

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

### Sodium hydroxymethanesulphinat:

Test Type : Maximisation Test  
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

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

---

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.

### **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 hydroxymethanesulphinat:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

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  
Remarks: Based on data from similar materials

Germ cell mutagenicity- Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

### **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

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

### **oxytetracycline:**

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

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

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

### **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

### **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 development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: positive

Reproductive toxicity - Assessment : 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

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 18 mg/kg body weight  
Result: No effects on fertility, No effect on reproduction capacity, No significant adverse effects were reported

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

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

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

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

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

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

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

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 development : Test Type: Development  
Species: Rat



# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

---

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 - Assessment : 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  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive  
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

### **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

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

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

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

### **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 w  
Target Organs : Gastrointestinal tract, Blood

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

---

Symptoms : constipation, Diarrhoea

### Sodium hydroxymethanesulphinate:

Species	: Rat
NOAEL	: 600 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
Method	: OECD Test Guideline 408
Remarks	: Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

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

### Experience with human exposure

#### Components:

##### **oxytetracycline:**

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

##### **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 : EC50 (Daphnia magna (Water flea)): > 500 mg/l  
aquatic invertebrates : Exposure time: 48 h

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

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

plants      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      :      EC50 (Daphnia magna (Water flea)): 621 mg/l  
aquatic invertebrates      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      :      EC50 (Anabaena): 0,032 mg/l  
plants      Exposure time: 72 h

NOEC (Anabaena): 0,0031 mg/l  
Exposure time: 72 h

M-Factor (Acute aquatic tox-      :      10  
icity)

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      :      10  
toxicity)

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

Toxicity to fish      :      LC50 (Pimephales promelas (fathead minnow)): 166,6 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other      :      EC50 (Daphnia magna (Water flea)): 80,1 mg/l  
aquatic invertebrates      Exposure time: 48 h  
Method: OECD Test Guideline 202

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

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 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC: 0,32 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 10 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Sodium hydroxymethanesulphinat:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 : > 1.000 mg/l  
Exposure time: 4 h  
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: 13,5 mg/l  
Exposure time: 35 d  
Species: Danio rerio (zebra fish)  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 5,6 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211  
Remarks: Based on data from similar materials

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

---

### 12.2 Persistence and degradability

#### Components:

##### **2-Pyrrolidone:**

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

##### **Sodium hydroxymethanesulphinate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 77 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: Based on data from similar materials

### 12.3 Bioaccumulative potential

#### Components:

##### **2-Pyrrolidone:**

Partition coefficient: n- : log Pow: -0,71  
octanol/water Method: OECD Test Guideline 107

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

Partition coefficient: n- : log Pow: 4,51  
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 Endocrine disrupting properties

#### Product:

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

### 12.7 Other adverse effects

No data available

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

### 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 handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### SECTION 14: Transport information

#### 14.1 UN number or ID 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   |                  |

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

---

**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  
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 aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

#### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
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



# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

### 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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
----	-----------------------	---------------------	---------------------

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

### Full text of H-Statements

H301	:	Toxic 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
Skin Irrit.	:	Skin irritation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	:	Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 4164056-00015      Date of last issue: 04.04.2023  
Date of first issue: 17.04.2019

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

### Further information

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

### Classification of the mixture:

Eye Irrit. 2	H319
Skin Sens. 1	H317
Repr. 1A	H360FD
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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.

# SAFETY DATA SHEET

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



## Oxytetracycline / Diclofenac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	4164056-00015	Date of first issue: 17.04.2019

---

NO / EN