

**Oxytetracycline / Diclofenac Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

**SECTION 1. IDENTIFICATION**

Product name : Oxytetracycline / Diclofenac Liquid Formulation

**Manufacturer or supplier's details**

Company : MSD

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

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Serious eye damage/eye irritation : Category 2A

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

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.

# Oxytetracycline / Diclofenac Liquid Formula- tion

Version 5.2      Revision Date: 19.05.2025      SDS Number: 1313892-00021      Date of last issue: 07.02.2025  
Date of first issue: 20.02.2017

H410 Very toxic to aquatic life with long lasting effects.

## Precautionary Statements

:

### Prevention:

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P261 Avoid breathing mist or vapors.  
P264 Wash skin thoroughly after handling.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
P391 Collect spillage.

### Storage:

P405 Store locked up.

### Disposal:

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

## Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
2-Pyrrolidone	616-45-5	>= 30 -< 50
Oxytetracycline	79-57-2	>= 20 -< 25
Benzyl alcohol	100-51-6	>= 1 -< 5
Magnesium oxide	1309-48-4	>= 1 -< 5
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	>= 0,25 -< 1
Sodium hydroxymethanesulphonate	149-44-0	>= 0,1 -< 1

## Oxytetracycline / Diclofenac Liquid Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

### SECTION 4. FIRST AID MEASURES

- |   |   |   |
|---|---|---|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.  |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention.  |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.  |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| Most important symptoms and effects, both acute and delayed | : | May cause an allergic skin reaction.<br>Causes serious eye irritation.<br>May damage fertility. May damage the unborn child.  |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).   |
| Notes to physician  | : | Treat symptomatically and supportively.   |

### SECTION 5. FIRE-FIGHTING MEASURES

- |  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                 | : | None known.   |
| Specific hazards during fire fighting          | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products                  | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

---

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

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

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**SECTION 7. HANDLING AND STORAGE**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Avoid breathing mist or vapors.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:

# Oxytetracycline / Diclofenac Liquid Formula- tion

Version 5.2      Revision Date: 19.05.2025      SDS Number: 1313892-00021      Date of last issue: 07.02.2025  
Date of first issue: 20.02.2017

Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Oxytetracycline	79-57-2	TWA	500 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Magnesium oxide	1309-48-4	CMP (Fumes)	10 mg/m <sup>3</sup>	AR OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
Sodium [2-[(2,6-dichloro-phenyl)amino]phenyl]acetate	15307-79-6	TWA	60 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				
		Wipe limit	6000 µg/100cm <sup>2</sup>	Internal

**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.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

### Personal protective equipment

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

Filter type : Combined particulates and organic vapor type

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

## Oxytetracycline / Diclofenac Liquid Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

Skin and body protection	:	<p>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</p> <p>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</p> <p>Work uniform or laboratory coat.</p> <p>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</p> <p>Use appropriate degowning techniques to remove potentially contaminated clothing.</p>
Hygiene measures	:	<p>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Contaminated work clothing should not be allowed out of the workplace.</p> <p>Wash contaminated clothing before re-use.</p> <p>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.</p>

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	light brown
Odor	:	No data available
Odor 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
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower	:	No data available

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

flammability limit

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1,05 - 1,18 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : 47,62 mm<sup>2</sup>/s

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

**SECTION 11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 5.000 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:**

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

**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 inhalation 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 toxicity  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 2,1 mg/l

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

**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 hydroxymethanesulphonate:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

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

**Benzyl alcohol:**

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

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

Result : irritating

**Sodium hydroxymethanesulphonate:**

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

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  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

**Magnesium oxide:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

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

Result : Mild eye irritation

**Sodium hydroxymethanesulphinate:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

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

May cause an allergic skin reaction.

**Respiratory sensitization**

Not classified based on available information.

**Components:****2-Pyrrolidone:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

Remarks : Based on data from similar materials

**Oxytetracycline:**

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

**Benzyl alcohol:**

Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Species : Humans  
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

**Magnesium oxide:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

**Sodium hydroxymethanesulphonate:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****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)

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

---

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

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.

**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

**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

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

---

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

**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 - 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

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

**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
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**Benzyl alcohol:**

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 103 weeks
Method	: OECD Test Guideline 451
Result	: negative

**Magnesium oxide:**

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 96 weeks
Result	: negative
Remarks	: Based on data from similar materials

**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

# Oxytetracycline / Diclofenac Liquid Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

---

Result: positive  
Remarks: Based on data from similar materials

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

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

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

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

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

Test Type: Embryo-fetal development  
Species: Dog  
Application Route: Intramuscular  
Embryo-fetal toxicity.: LOAEL: 20,75 mg/kg body weight

## Oxytetracycline / Diclofenac Liquid Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

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Result: Skeletal and visceral variations ., Postimplantation loss.

Reproductive toxicity - Assessment : 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 fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### **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 fetal development : 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

### **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 fetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Development  
Species: Rabbit  
Application Route: Oral

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

Developmental Toxicity: LOAEL: 5 mg/kg body weight  
Result: Embryo-fetal 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

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive

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**

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

## Oxytetracycline / Diclofenac Liquid Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

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

### Benzyl alcohol:

Species : Rat  
 NOAEL : 1,072 mg/l  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 28 Days  
 Method : OECD Test Guideline 412

### Magnesium oxide:

Species : Rat  
 NOAEL :  $\geq 1.000$  mg/kg  
 Application Route : Ingestion  
 Exposure time : 28 Days  
 Method : OECD Test Guideline 407  
 Remarks : Based on data from similar materials

### 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

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

Species	: Baboon
NOAEL	: 0,5 mg/kg
LOAEL	: 5 mg/kg
Application Route	: Oral
Exposure time	: 52 w
Target Organs	: Gastrointestinal tract, Blood
Symptoms	: constipation, Diarrhea

**Sodium hydroxymethanesulphinate:**

Species	: Rat
NOAEL	: 600 mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks
Method	: OECD Test Guideline 408

**Aspiration toxicity**

Not classified based on available information.

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

Ingestion	: Symptoms: Gastrointestinal disturbance, tooth discoloration Remarks: May cause birth defects.
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**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Ingestion	: Symptoms: Abdominal pain, Diarrhea, constipation, heartburn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash
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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****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

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

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 (*Moina macrocopa* (Water flea)): 126,7 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)

M-Factor (Chronic aquatic : 10  
toxicity)

Toxicity to microorganisms : EC50 (activated sludge): 17,9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC (activated sludge): 0,2 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Benzyl alcohol:**

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): 460 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (*Daphnia magna* (Water flea)): 230 mg/l  
aquatic invertebrates Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (*Pseudokirchneriella subcapitata* (green algae)): 770  
plants 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

## Oxytetracycline / Diclofenac Liquid Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
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

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

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

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

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

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**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 fish (Chronic toxicity)	:	NOEC (Danio rerio (zebra fish)): 13,5 mg/l Exposure time: 35 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10 (Daphnia magna (Water flea)): 8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	NOEC: 10 mg/l Exposure time: 4 h

**Persistence and degradability****Components:****2-Pyrrolidone:**

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

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d
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**Sodium hydroxymethanesulphinate:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 77 % Exposure time: 28 d Method: OECD Test Guideline 301B
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**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

**Bioaccumulative potential****Components:****2-Pyrrolidone:**

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

**Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1,05

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

Partition coefficient: n-octanol/water : log Pow: 4,51

**Sodium hydroxymethanesulphinate:**

Partition coefficient: n-octanol/water : log Pow: < 0,3

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Oxytetracycline)

Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

**IATA-DGR**

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Oxytetracycline)

Class : 9

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

**IMDG-Code**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Oxytetracycline)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

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

Not applicable for product as supplied.

**Special precautions for user**

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

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

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

**SECTION 16. OTHER INFORMATION**

Revision Date : 19.05.2025  
Date format : dd.mm.yyyy

**Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

**Oxytetracycline / Diclofenac Liquid Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 07.02.2025
5.2	19.05.2025	1313892-00021	Date of first issue: 20.02.2017

compile the Material Safety  
Data SheeteChem Portal search results and European Chemicals Agen-  
cy, <http://echa.europa.eu/>**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AR OEL	:	Argentina. Occupational Exposure Limits

ACGIH / TWA	:	8-hour, time-weighted average
AR OEL / CMP	:	TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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