

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 1 von 10 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Oxytetracycline hydrochloride

Art.-No.: 700116

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

1.1 Product identifier

Product name: Oxytetracycline hydrochloride

CAS-Nr.: 2058-46-0

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

Relevant Identified uses:

Active pharmaceutical ingredient (API)

Uses advised against:

This product should not be used for purposes other than the applications referred to above.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier

Euro OTC Pharma GmbH

Edisonstr. 6

59199 Bönen

Telephone / fax / email

02383 / 922020

/ 02383 / 92202150

/ E-Mail: info@euro-otc.com

1.4 Emergency telephone number

0361 / 730730 (Gemeinsames Giftnotrufzentrum, Nordhäuser Str. 74, 99089 Erfurt) (Germany)

SECTION 2: Hazards identification:

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: Reproductive toxicity (Category 2), H361d

Classification according to Directive 67/548/EWG: Not classified.

2.2 Label elements

Label elements According to Regulation (EC) No 1272/2008

Pictogram:



Signal word: Warning

Hazard statements:

H361d: Suspected of damaging the unborn child.

Precautionary statements:

P281: Use personal protective equipment as required.

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 2 von 10 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Oxytetracycline hydrochloride	Art.-No.: 700116
---	-------------------------

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance: Oxytetracycline hydrochloride

Formula: $C_{22}H_{24}N_2O_9 \cdot HCl$

Molecular weight: 496,89 g/mol

CAS-Nr.: 2058-46-0

EC No.: 218-161-2

Classification: Repr. 2; H361d

Concentration: ≤ 100 %

3.2 Mixtures

- Not Applicable.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

Inhalation:

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact:

Wash off with soap and plenty of water. Consult a physician.

Eye contact:

Flush eyes with water as a precaution.

If swallowed:

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 3 von 10 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Oxytetracycline hydrochloride	Art.-No.: 700116
---	-------------------------

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x), Hydrogen chloride gas

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

6. SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 4 von 10 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Oxytetracycline hydrochloride	Art.-No.: 700116
---	-------------------------

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
 Store under inert gas. Light sensitive. Air sensitive.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Individual protection measures

Eye/face protection: Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body protection: Impervious clothing, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a fullface particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 5 von 10 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Oxytetracycline hydrochloride

Art.-No.: 700116

and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Environmental exposure controls: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties Appearance

General Information

Appearance:	Form: crystalline
	Color: yellow
Odor:	No data available
Odor Threshold:	No data available
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper/lower flammability or explosive limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Relative density:	No data available
Water solubility:	No data available
Partition coefficient: n-octanol/water	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 6 von 10 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Oxytetracycline hydrochloride	Art.-No.: 700116
---	-------------------------

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid:

Air Light.

10.5 Incompatible materials:

Bases

Hazardous decomposition products

- 10.6** Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NO_x), Hydrogen chloride gas
 Other decomposition products - No data available
 In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Mouse - 6.696 mg/kg

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification.

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Laboratory experiments have shown teratogenic effects. Exposure to high concentrations during pregnancy can result in mild teratogenic effects. Suspected human reproductive toxicant Suspected of damaging the unborn child.

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Q18225000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2 Additional Information

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 7 von 10 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Oxytetracycline hydrochloride	Art.-No.: 700116
---	-------------------------

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.

RTECS: QI8225000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish LC50 - Salvelinus namaycush - < 200 mg/l - 96 h

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

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

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 9 von 10 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Oxytetracycline hydrochloride

Art.-No.: 700116

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET Conforms to Regulation (EC) No. 1907/2006 (REACH)	Date: Page: Vers.-No.	05.02.2025 10 von 10 02
---	--	-----------------------------	-------------------------------

Art.-Ref.: Oxytetracycline hydrochloride	Art.-No.: 700116
---	-------------------------

Data Sheet Issuing Department: Quality Assurance

Full text of H-Statements referred to under sections 2 and 3.

H361d Suspected of damaging the unborn child.

Abbreviations and acronyms:

ADR = European Agreement concerning the International Carriage of Dangerous Goods by Road.
 ADN = European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
 ATE = Acute Toxicity Estimates.
 CAO = Cargo Aircraft Only.
 CAS = Chemical Abstracts Service.
 CLP = Classification, Labelling, and Packaging of Chemicals.
 DIN = German Institute for Standardization.
 DNEL = Derived No-Effect Level.
 EC50 = Median Effective Concentration that causes a defined effect other than death in a test population.
 EG = European Community.
 EN = European Standards.
 IARC = International Agency for Research on Cancer.
 IATA = International Air Transport Association.
 IBC Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk.
 IMDG = International Maritime Dangerous Goods Code.
 ISO = International Organization for Standardization.
 STEL = Short-Term Exposure Limit.
 LC50 = Lethal Concentration affecting 50% of the observed population.
 LD50 = Lethal Dose affecting 50% of the observed population.
 MAK = Maximum Workplace Concentration.
 MARPOL = International Convention for the Prevention of Pollution from Ships.
 NEN = Dutch Standards.
 NOEC = No Observed Effect Concentration.
 OEL = Occupational Exposure Limit.
 OECD = Organisation for Economic Co-operation and Development.
 PBT = Persistent, Bioaccumulative, and Toxic.
 PNEC = Predicted No-Effect Concentration.
 PPM = Parts Per Million.
 RID = Regulations concerning the International Carriage of Dangerous Goods by Rail.
 TWA = Time-Weighted Average.
 UN Number = UN Number for the Transport of Dangerous Goods.
 vPvB = Very Persistent and Very Bioaccumulative.

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

The above information is based on the current state of our knowledge and experience. They describe the products with regard to safety requirements and do not represent a guarantee of properties. The recipient of our product is responsible for observing existing laws and regulations.