

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 1 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate

Art.-No.: 702343

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

1.1 Product identifier

Product name: Amoxicillin trihydrate

Index-Nr.: -

EG-Nr.: 933-899-1

CAS-Nr.: 61336-70-7

REACH- Registration number.: -

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

Identified uses:

- Active pharmaceutical ingredient (API)

Uses advised against:

- Any use other than the active pharmaceutical ingredient (API)

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
- info@euro-otc.com

1.4 Emergency telephone number

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

ChemTel Contract Number MIS5311335 –

USA and Canada: +1-800-255-3924 (toll free),

Australia: +1-300-954-583,

Brazil: +0-800-591-6042,

China: +400-120-0751,

India: +000-800-100-4086,

Mexico: 800-099-0731,

International phone number: +1-813-248-0585 (collect calls accepted)

SECTION 2: Hazards identification:

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 (CLP/GHS)

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 2 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate

Art.-No.: 702343

Resp. Sens. 1 ; H334 - Sensitisation to the respiratory tract : Category 1 ; May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sens. 1 ; H317 - Skin sensitisation : Category 1 ; May cause an allergic skin reaction.

2.2 Label elements

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

Hazard pictograms:



Signal word: Danger

Hazard statements:

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement(s)

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor

P362+P364 Take off contaminated clothing and wash it before reuse.

P321 Specific treatment (see on this label)

2.3 Other hazards

- None

SECTION 3: Composition/information on ingredients

3.1 Substances

Main component of the fabric

Product/ingredient name: Amoxicillin trihydrate

Index-Nr.:

EC-Nr.: 248-003-8

CAS-Nr.: 61336-70-7

Chemical formula: $C_{16}H_{19}N_3O_5S \cdot 3 H_2O$

Molecular weight: 419,4

Purity: 100% [mass]

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 3 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate

Art.-No.: 702343

SECTION 4: First aid measures

4.1 Description of first aid measures

- Remove contaminated, saturated clothing immediately. After contact with skin, wash immediately with plenty of water and soap. In case of skin reactions, consult a physician. After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. If accidentally ingested, seek immediate medical attention, NEVER induce vomiting. Remove victim out of the danger area. In case of inhalation take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

4.2 Most important symptoms and effects, both acute and delayed Over-exposure signs/symptoms

- Accidental contact may result in serious respiratory difficulties, alteration of the central nervous system and in extreme cases, unconsciousness

4.3 Indication of any immediate medical attention and special treatment needed

- Request immediate medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

SECTION 5: Firefighting measures

The product does not present any particular risk in case of fire.

5.1 Extinguishing media

Suitable extinguishing media:

- Extinguish with carbon dioxide, fire-extinguishing powder, alcohol resistant foam or waterspray.

Unsuitable extinguishing media:

- Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture

- In case of fire may be liberated: Pyrolysis products, toxic

5.3 Advice for firefighters

- Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.
- Prevent the products used to fight the fire from going into drains, sewers, or waterways.

Special protective equipment for firefighters

- According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 4 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate

Art.-No.: 702343

6. **SECTION 6: Accidental release measures**

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

- Clear spills immediately.

For non-emergency personnel

- Wear a self-contained breathing apparatus and chemical protective clothing. Remove persons to safety.

For emergency responders

- Eliminate possible ignition points and ventilate the area. No smoking. Avoid breathing fumes. For exposure control and individual protection measures, see section 8.

6.2 **Environmental precautions**

- Do not allow to enter into surface water or drains. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities. Retain contaminated washing water and dispose it.

6.3 **Methods and materials for containment and cleaning up**

For containment

- Collect in closed and suitable containers for disposal.

For cleaning up

- The contaminated area should be cleaned up immediately with: Water Soak up inert absorbent and dispose as waste requiring special attention. Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Avoid dust formation.

6.4 **Reference to other sections**

- For exposure control and individual protection measures, see section 8.
- For later elimination of waste, follow the recommendations under section 13.

SECTION 7: Handling and storage

7.1 **Precautions for safe handling**

Protective measures

- When using do not eat, drink, smoke, sniff. Wear personal protection equipment (refer to section 8)

Measures to prevent aerosol and dust generation

- Use only in well-ventilated areas. Do not breathe gas/fumes/vapour/spray. Do not breathe dust

Environmental precautions

- Use appropriate container to avoid environmental contamination

Specific requirements or handling rules

- Handle and open container with care

Advices on general occupational hygiene

- Handle and open container with care



 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 5 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate

Art.-No.: 702343

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

- Storage temperature: +2 - +8°C
- Keep in a cool, well-ventilated place. Protect against UV-radiation/sunlight Humidity.

Requirements for storage rooms and vessels

- Only use containers specifically approved for the substance/product.

Hints on joint storage

- Store at least 3 metres apart from: Chemicals/products that react together readily
- Storage class (TRGS 510) : 13

7.3 Specific end use(s)

- Industry and sector-specific guidelines

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

- The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls

Only wear fitting, comfortable and clean protective clothing

Individual protection measures, such as personal protective equipment

Eyeface protection

- Eye glasses with side protection Face protection shield EN 166



Skin protection

Hand protection

- Tested protective gloves must be worn EN ISO 374 The quality of the protective
- gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.



Body protection

- Full protection suit Wash contaminated clothing prior to re-use



Respiratory protection

- If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.
- The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded,



 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 6 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate

Art.-No.: 702343

self-contained breathing apparatus must be used. Particle filter device (EN 143).

Thermal hazards

- No information available.

Environmental exposure controls:

- No information available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties Appearance

General Information

Physical state:	Solid
Color:	Almost White
Odor:	No information available
Odor threshold:	No information available
pH:	No information available
log P O/W	No information available
Flow time	No information available
Melting point/freezing point:	No information available
Initial boiling point and boiling range:	No information available
Flammability:	No information available
Flash point:	No information available
Evaporation rate	No information available
Lower and upper explosion limit:	No information available
Vapor pressure:	No information available
Vapor density:	No information available
Density	None
Solvent separation test	Not applicable
Solubility(ies)	No information available
Partition coefficient: n-octanol/water:	No information available
Auto-ignition temperature:	No information available
Decomposition temperature:	No information available
Viscosity:	No information available

9.2 Other information

- No further data

SECTION 10: Stability and reactivity

10.1 Reactivity

- The product does not present hazards by their reactivity.

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 7 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate

Art.-No.: 702343

10.2 Chemical stability

- The product is chemically stable under recommended conditions of storage, use and temperature. Safe handling: see section 7

10.3 Possibility of hazardous reactions

- The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid:

- Avoid direct sunlight, and avoid forming dust fog to cause heat release

10.5 Incompatible materials:

- Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products

- In case of fire may be liberated: Hazardous combustion products

SECTION 11: Toxicological information

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

Acute toxicity-Ingestion

- No information available

Corrosion

Skin corrosion/irritation

- No information available

Serious eye damage/irritation

- Direct contact with eyes may cause slight irritation

Skin sensitization

- No irritation after direct contact

Respiratory sensitization

- No information available

STOT-single exposure

- No information available

STOT-repeated exposure

- No information available

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

- No information available.

Germ cell mutagenicity

- No information available.

Reproductive toxicity

- No information available.

Aspiration hazard

- No information available

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 8 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate	Art.-No.: 702343
--	-------------------------

Additional hazard of reproductive toxicity

- No information available

11.2 Information on other hazards

Endocrine disrupting properties

- Substance is not listed

SECTION 12: Ecological information

12.1 Toxicity

- No information available

12.2 Persistence and degradability

- No information available

12.3 Bioaccumulative potential

- No information available

12.4 Mobility in soil

- No information available

12.5 Results of PBT and vPvB assessment

- This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII

12.6 Endocrine disrupting properties

- The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

- Additional ecological information: -
- General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation. Follow the provisions of Directive 2008/98/EC regarding waste management

Product/Packaging disposal

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 9 von 11 02
---	--	-----------------------------	------------------------------

Art.-Ref.: Amoxicillin trihydrate

Art.-No.: 702343

Waste treatment options

- Recycle according to official regulations. Evidence for disposal must be provided.

Appropriate disposal / Product

- Dispose of waste according to applicable legislation.

Appropriate disposal / Package

- Contaminated packages must be completely emptied and can be re-used following proper cleaning. Packing which cannot be properly cleaned must be disposed of. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.1 UN number or ID number

This product is not regulated as hazardous goods

14.2 14.2 UN proper shipping name

ADR, IMDG

- Not Dangerous Goods

IATA

- Not Dangerous Goods

14.3 Transport Hazard Class:

-

14.4 Packing Group

-

14.5 Environmental hazards:

Marine pollutant: No

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

14.6 Special precautions for user

- No further relevant information available.

14.7 Transport in bulk according to Annex 11 of MARPOL and the IBC code

- No further relevant information available.

SECTION 15: Regulatory information

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 10 von 11 02
---	--	-----------------------------	-------------------------------

Art.-Ref.: Amoxicillin trihydrate	Art.-No.: 702343
--	-------------------------

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

- Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Classification according to Regulation (EC) No 1272/2008 [CLP] according to Regulation (EU) No. 2020/878

EU legislation

Authorisations and/or restrictions on use

Restrictions on use

- Regulation (EC) No. 1907/2006 (REACH), Annex XVII (restrictions)
- Use restriction according to REACH annex XVII, no.: 3

National regulations

- Water hazard class
- Class: nwg (Non-hazardous to water)

15.2 Chemical Safety Assessment

- No Chemical Safety Assessment (CSA) has been carried out
-

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 11 von 11 02
---	--	-----------------------------	-------------------------------

Art.-Ref.: Amoxicillin trihydrate	Art.-No.: 702343
--	-------------------------

SECTION 16: Other information

Relevant H- and EUH-phrases (Number and full text)

- H317 May cause an allergic skin reaction.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Training advice

- None

Key literature references and sources for data:

- None

Contact person: Mr. Dr. Abdulsalam Adam

Abbreviations and acronyms:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
ASTM: ASTM International, originally known as American Society for Testing and Materials (ASTM)
EINECS: European Inventory of Existing Commercial Chemical Substances
EC50: Effective Concentration 50 (Maximum Effective Concentration for 0% of Individuals)
LC50: Lethal Concentration 50 (Lethal Concentration for 50% of Individuals)
IC50: Inhibitor Concentration 50 (Inhibitory Concentration for 50% of Individuals)
NOEL: No Observed Effect Level (Maximum dose without effect)
DNEL: Derived No Effect Level (Derived no-effect dose)
DMEL: Derived Minimum Effect Level (Derived dose of minimal effect)
CLP: Classification, Labelling and Packaging
CSR: Chemical Safety Report
LD50: Lethal Dose 50 (Lethal Dose for 50% of Individuals)
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
Codice IMDG: International Maritime Dangerous Goods code
PBT: Persistent, bioaccumulative and toxic
RID: Regulations concerning the international rail transport of Dangerous Goods
STEL: Short term exposure limit

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemical substances and mixtures (REACH)

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.