according to WHS Regulations

1 Identification

- · Product identifier
- · Trade name: Amoxicilline trihydrate
- · Article number: 100132, 700636
- · CAS Number:
- 61336-70-7
- · EC number:
- 248-003-8
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Additive for cosmetic or pharmaceutic preparations

· Details of the supplier of the safety data sheet

Manufacturer/Supplier: Fagron Services B.V. Molenwerk 13, UITGEEST, 1911DB Netherlands Phone: +31251361400

Supplier Azelis Australia Suite 217 117 Old Pittwater Road Brookvale NSW 2100 Australia Phone: +61 0299392188 Fax: +61 0299392799 e-mail: info@azelis.com.au

• Further information obtainable from: info@fagron.com.au • Emergency telephone number:

In case of emergency, please call your local poisons: Emergency Australia: 13 11 26 Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE: +44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65 3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333 (English only)

2 Hazard(s) Identification

· Classification of the substance or mixture

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.Skin Sens. 1 H317 May cause an allergic skin reaction.

· Label elements

· GHS label elements

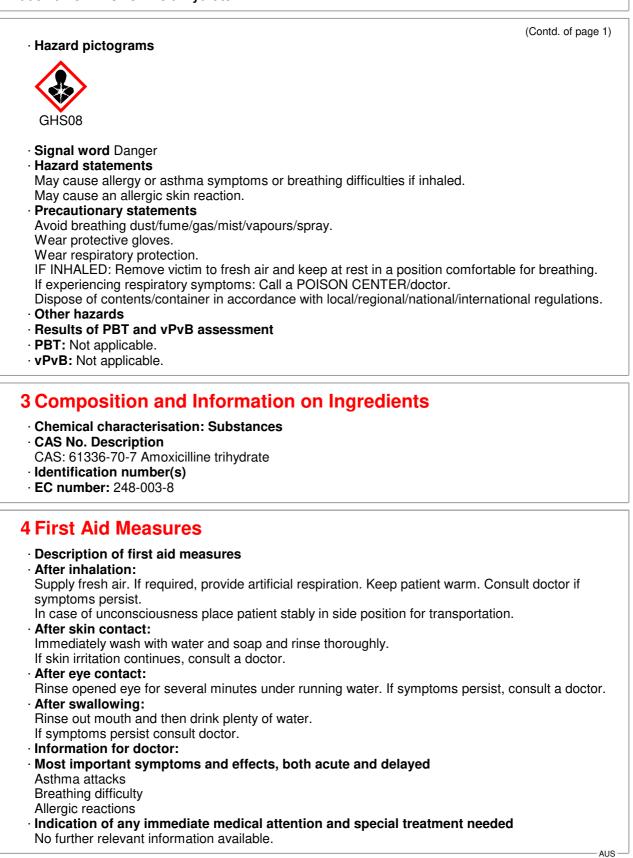
The substance is classified and labelled according to the Globally Harmonised System (GHS).

(Contd. on page 2)



according to WHS Regulations

Trade name: Amoxicilline trihydrate



(Contd. on page 3)



according to WHS Regulations

Trade name: Amoxicilline trihydrate

(Contd. of page 2)

5 Fire Fighting Measures Extinguishing media Suitable extinguishing agents: Carbon dioxide Fire-extinguishing powder Water spray Use fire extinguishing methods suitable to surrounding conditions. For safety reasons unsuitable extinguishing agents: Water with full jet Special hazards arising from the substance or mixture In case of fire, the following can be released: Carbon monoxide (CO) Nitrogen oxides (NOx) Can form explosive gas-air mixtures.

- · Advice for firefighters
- Protective equipment:
- Wear fully protective suit.

Wear self-contained respiratory protective device.

6 Accidental Release Measures

- Personal precautions, protective equipment and emergency procedures Wear protective clothing.
 Ensure adequate ventilation
 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
 Methods and material for containment and cleaning up:
- Dispose contaminated material as waste according to item 13.
- Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and Storage

- · Handling:
- · Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Store away from oxidising agents.
- · Further information about storage conditions:
- Store in dry conditions.

Protect from heat and direct sunlight.

Store receptacle in a well ventilated area.

· Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

• Additional information about design of technical facilities: No further data; see item 7.

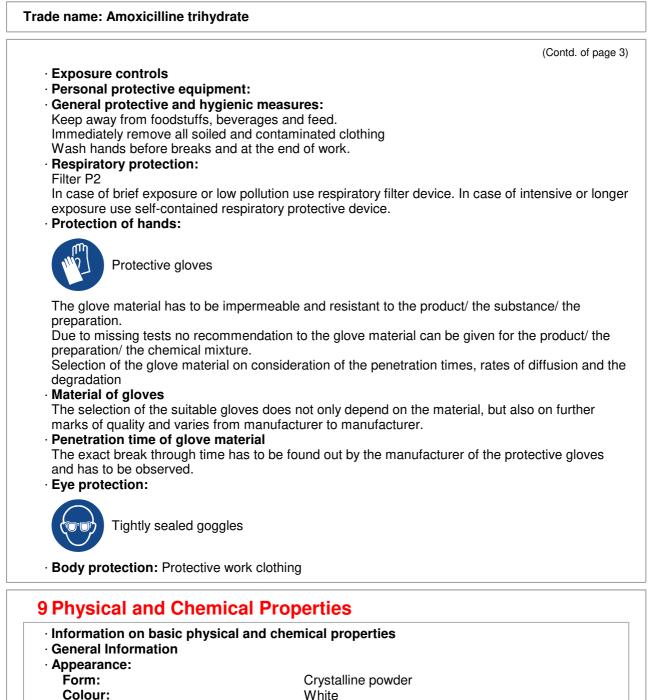
- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists valid during the making were used as basis.

(Contd. on page 4)

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Colour:
· Odour:
• • • •

Odour: Odour threshold:	Characteristic Not determined.
· pH-value:	3.5–5.5
 Change in condition Melting point/freezing point: Initial boiling point and boiling range 	135–136°C a: 743°C
· Flash point:	Not applicable.
· Flammability (solid, gas):	Product is not flammable.
	(Cantal on page E)

(Contd. on page 5) - AUS



according to WHS Regulations

Trade name: Amoxicilline trihydrate

	(Contd. of page 4)
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
 Explosion limits: Lower: Upper: 	Not determined. Not determined.
· Vapour pressure:	Not applicable.
 Density at 20°C: Relative density Vapour density Evaporation rate 	1.54 g/cm ³ Not determined. Not applicable. Not applicable.
 Solubility in / Miscibility with water: 	Not determined.
· Partition coefficient: n-octanol/water:	-0.06048075
 Viscosity: Dynamic: Kinematic: 	Not applicable. Not applicable.
· Other information	No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- Chemical stability
- Thermal decomposition / conditions to be avoided:
- No decomposition if used according to specifications.
- Possibility of hazardous reactions Reacts with strong acids and oxidising agents.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- Hazardous decomposition products:

Carbon dioxide Carbon monoxide Nitrogen oxides (NOx) Ammonia Hydrogen sulphide Mercaptans

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity

· LD/LC50 values relevant for classification:

Oral LD50 >25000 mg/kg (mouse)

>8000 mg/kg (rat)

• **Respiratory or skin sensitisation** Sensitisation possible through inhalation.

(Contd. on page 6)



according to WHS Regulations

Trade name: Amoxicilline trihydrate

(Contd. of page 5)

Sensitisation possible through skin contact.

12 Ecological Information

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · 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.

- Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:

• **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

UN-Number ADG, IMDG, IATA	not regulated	
UN proper shipping name ADG, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADG, ADN, IMDG, IATA Class	not regulated	
Packing group ADG, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	
Transport in bulk according to Ann Marpol and the IBC Code	ex II of Not applicable.	
UN "Model Regulation":	not regulated	

(Contd. on page 7)



according to WHS Regulations

Page 7/7 Printing date 20.04.2023 Revision: 19.04.2023 Version number 1.4

Trade name: Amoxicilline trihydrate

(Contd. of page 6)

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15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals Substance is not listed.
- Standard for the Uniform Scheduling of Medicines and Poisons Substance is not listed.
- Australia: Priority Existing Chemicals Substance is not listed.
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · National regulations:
- · Other regulations, limitations and prohibitive regulations
- Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing SDS: Product Safety Department
- Contact:
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Resp. Sens. 1: Respiratory sensitisation – Category 1 Skin Sens. 1: Skin sensitisation – Category 1

