

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, UITGEEEST, 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)

AUS

Trade name: Amoxicilline trihydrate

(Contd. of page 1)

· **Hazard pictograms**



GHS08

· **Signal word** Danger

· **Hazard statements**

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

May cause an allergic skin reaction.

· **Precautionary statements**

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

Wear protective gloves.

Wear respiratory protection.

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· **Chemical characterisation: Substances**

· **CAS No. Description**

CAS: 61336-70-7 Amoxicilline trihydrate

· **Identification number(s)**

· **EC number:** 248-003-8

4 First Aid Measures

· **Description of first aid measures**

· **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed**

Asthma attacks

Breathing difficulty

Allergic reactions

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

AUS

(Contd. on page 3)

Trade name: Amoxicilline trihydrate

(Contd. of page 2)

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
 - Carbon dioxide
 - Fire-extinguishing powder
 - Water sprayUse 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)

AUS

Trade name: Amoxicilline trihydrate

(Contd. of page 3)

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
- **Respiratory protection:**
Filter P2
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

9 Physical and Chemical Properties

- | | |
|--|---------------------------|
| · Information on basic physical and chemical properties | |
| · General Information | |
| · Appearance: | |
| Form: | Crystalline powder |
| Colour: | White |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |
| · pH-value: | 3.5–5.5 |
| · Change in condition | |
| Melting point/freezing point: | 135–136°C |
| Initial boiling point and boiling range: | 743°C |
| · Flash point: | Not applicable. |
| · Flammability (solid, gas): | Product is not flammable. |

(Contd. on page 5)

AUS

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:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density at 20°C:	1.54 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Not determined.
· Partition coefficient: n-octanol/water:	-0.06048075
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	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 (NO_x)
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)

AUS

Trade name: Amoxicilline trihydrate

Sensitisation possible through skin contact.

(Contd. of page 5)

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 Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

AUS

(Contd. on page 7)

Trade name: Amoxicilline trihydrate

(Contd. of page 6)

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

AUS