

Amoxicillin trihydrate

Safety Data Sheet

according to Regulation (EU) 2015/830

Date of issue: 13/10/2010 Revision date: 11/10/2017

Supersedes 03/08/2011

A0101

Version: 2.0

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

1.1. Product identifier

Product form : Substance
 Trade name : Amoxicillin trihydrate
 EC-No. : 248-003-8
 CAS-No. : 61336-70-7
 Product code : A0101
 Formula : C₁₆H₁₉N₃O₅S · 3H₂O

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

1.2.1. Relevant identified uses

Main use category : Professional use
 Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Duchefa Biochemie B.V.
 A. Hofmanweg 71
 2031 BH Haarlem - The Netherlands
 T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.nl

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
World Health Organization world directory of poison centres	http://apps.who.int/poisoncentres/	Consult website for a local poison centre

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Respiratory sensitisation, Category 1 H334
 Skin sensitisation, Category 1 H317

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) :

: Danger

Hazard statements (CLP) :

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

Precautionary statements (CLP) :

: P261 - Avoid breathing dust.
P280 - Wear protective clothing, face protection, eye protection, protective gloves.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER/doctor
P302+P352 - IF ON SKIN: Wash with plenty of water.
P273 - Avoid release to the environment**2.3. Other hazards**

No additional information available

SECTION 3: Composition/information on ingredients**3.1. Substances**Name : Amoxicillin trihydrate
CAS-No. : 61336-70-7
EC-No. : 248-003-8

Name	Product identifier	%
Amoxicillin trihydrate	(CAS-No.) 61336-70-7 (EC-No.) 248-003-8	>= 95

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures**4.1. Description of first aid measures**First-aid measures after inhalation : Assure fresh air breathing. Call a physician immediately. If not breathing, give artificial respiration.
First-aid measures after skin contact : Wash skin with mild soap and water. Get medical advice/attention.
First-aid measures after eye contact : Ensure adequate flushing of eyes by separating eyelids with the fingers. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention.
First-aid measures after ingestion : Rinse mouth. Get medical advice/attention.**4.2. Most important symptoms and effects, both acute and delayed**

Symptoms/effects : May cause an allergic skin reaction. This material or its emissions may induce blood disorders and/or aggravate pre-existing blood disorders.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water. Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Thermal decomposition generates : CO_x. NO_x. SO_x.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Other information : Prevent fire fighting water from entering the environment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

Measures in case of dust release : Avoid dust formation.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Do not allow product to spread into the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. Dispose in a safe manner in accordance with local/national regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Hygroscopic. Store in dry, well-ventilated area. Keep container tightly closed and protected from light. Store at room temperature.

7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Filter type P3 (EN 143)

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 419,5 g/mol
Colour	: White.
Odour	: No data available
Odour threshold	: No data available
pH	: 3,5 - 5,5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: > 194 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. COx. NOx. SOx.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Not classified

Amoxicillin trihydrate (61336-70-7)	
LD50 oral rat	> 15000 mg/kg
Skin corrosion/irritation	: Not classified pH: 3,5 - 5,5
Serious eye damage/irritation	: Not classified pH: 3,5 - 5,5
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: Gastrointestinal complaints. This material or its emissions may induce blood disorders and/or aggravate pre-existing blood disorders.
Other information	: See actual entry in RTECS for complete information: XH8310000.

SECTION 12: Ecological information**12.1. Toxicity**

Amoxicillin trihydrate (61336-70-7)	
LC50 fish 1	0,0022 mg/l
EC50 72h algae (1)	630 mg/l

12.2. Persistence and degradability

Amoxicillin trihydrate (61336-70-7)	
Persistence and degradability	Product is biodegradable.
Biodegradation	88 %

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations.
Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

ADR	IMDG	IATA
14.1. UN number		
Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name		
Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)		
Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable
14.4. Packing group		
Not applicable	Not applicable	Not applicable
14.5. Environmental hazards		
Not applicable	Not applicable	Not applicable
No supplementary information available		

14.6. Special precautions for user**. Overland transport**

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Amoxicillin trihydrate is not on the REACH Candidate List

Amoxicillin trihydrate is not on the REACH Annex XIV List

15.1.2. National regulations**Germany**

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

Denmark

Recommendations Danish Regulation : Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

1.4	Emergency number	Modified	
2	Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
9.1	Melting point	Modified	

Abbreviations and acronyms:

ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC

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DSD	Dangerous Substances Directive 67/548/EEC
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

Data sources : Supplier. ECHA (European Chemicals Agency). REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

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

SDS Biochemicals version 2017

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product