

according to Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Revision Date 24-Feb-2024 Revision Number 3

# SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Product Description: <u>Amoxicillin trihydrate</u>

**Cat No.**: **J61290 CAS No** 61336-70-7

Molecular Formula C16 H19 N3 O5 S.3H2 O

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

Recommended Use Laboratory chemicals.
Uses advised against No Information available

#### 1.3. Details of the supplier of the safety data sheet

Company

Avocado Research Chemicals Ltd. (Part of Thermo Fisher Scientific)

Shore Road, Heysham Lancashire, LA3 2XY, United Kingdom

Office Tel: +44 (0) 1524 850506 Office Fax: +44 (0) 1524 850608

E-mail address begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

# **SECTION 2: HAZARDS IDENTIFICATION**

## 2.1. Classification of the substance or mixture

#### CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

#### **Physical hazards**

Based on available data, the classification criteria are not met

#### **Health hazards**

Respiratory Sensitization Category 1 (H334)
Skin Sensitization Category 1 (H317)

ALFAAJ61290

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#### **Environmental hazards**

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

#### 2.2. Label elements



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 Statements**

P280 - Wear protective gloves/protective clothing

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

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

P285 - In case of inadequate ventilation wear respiratory protection

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

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

#### 2.3. Other hazards

Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (vPvB)

This product does not contain any known or suspected endocrine disruptors

# **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.1. Substances

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Amoxicillin trihydrate	61336-70-7		<=100	Skin Sens. 1 (H317) Resp. Sens. 1 (H334)

Full text of Hazard Statements: see section 16

# **SECTION 4: FIRST AID MEASURES**

## 4.1. Description of first aid measures

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**General Advice** If symptoms persist, call a physician.

**Eye Contact** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

**Skin Contact** Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

**Ingestion** Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

**Inhalation** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

**Self-Protection of the First Aider** No special precautions required.

#### 4.2. Most important symptoms and effects, both acute and delayed

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause allergic skin reaction. Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing

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

Notes to Physician Treat symptomatically.

# **SECTION 5: FIREFIGHTING MEASURES**

#### 5.1. Extinguishing media

#### **Suitable Extinguishing Media**

Carbon dioxide (CO 2). Powder. Water spray. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

## Extinguishing media which must not be used for safety reasons

No information available.

#### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

#### **Hazardous Combustion Products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Nitrogen oxides (NOx), Sulfur oxides.

#### 5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

# **SECTION 6: ACCIDENTAL RELEASE MEASURES**

#### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

#### 6.2. Environmental precautions

Should not be released into the environment. See Section 12 for additional Ecological Information.

#### 6.3. Methods and material for containment and cleaning up

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Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

#### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

# **SECTION 7: HANDLING AND STORAGE**

#### 7.1. Precautions for safe handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid ingestion and inhalation. Avoid dust formation. Do not get in eyes, on skin, or on clothing.

## **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

#### 7.2. Conditions for safe storage, including any incompatibilities

Keep refrigerated.

Technical Rules for Hazardous Substances (TRGS) 510 Class 11 Storage Class (LGK) (Germany)

#### 7.3. Specific end use(s)

Use in laboratories

# **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

## 8.1. Control parameters

#### **Exposure limits**

List source(s):

#### **Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

### Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

No information available

#### **Predicted No Effect Concentration (PNEC)**

No information available.

#### 8.2. Exposure controls

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**Engineering Measures** 

None under normal use conditions.

Personal protective equipment

**Eye Protection** Wear safety glasses with side shields (or goggles) (European standard - EN 166)

**Hand Protection** Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
Neoprene	recommendations			
Natural rubber				
PVC				

Skin and body protection Long sleeved clothing.

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

No protective equipment is needed under normal use conditions. **Respiratory Protection** 

Large scale/emergency use Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits

are exceeded or if irritation or other symptoms are experienced

Recommended Filter type: Particle filter

Small scale/Laboratory use Maintain adequate ventilation

**Environmental exposure controls** No information available.

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1. Information on basic physical and chemical properties

Solid **Physical State** 

**Appearance** White - Off-white No information available Odor **Odor Threshold** No data available **Melting Point/Range** No data available **Softening Point** No data available **Boiling Point/Range** No information available

Flammability (liquid) Not applicable Solid

Flammability (solid,gas) No information available **Explosion Limits** No data available

**Flash Point** No information available Method - No information available

**Autoignition Temperature** No data available No data available **Decomposition Temperature** 

No information available Hq

Solid Viscosity Not applicable

Water Solubility No information available Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

No data available **Vapor Pressure Density / Specific Gravity** No data available **Bulk Density** No data available **Vapor Density** Not applicable

Solid

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Particle characteristics No data available

9.2. Other information

Molecular FormulaC16 H19 N3 O5 S.3H2 OMolecular Weight419.45 (365.40anhy)Evaporation RateNot applicable - Solid

# **SECTION 10: STABILITY AND REACTIVITY**

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous PolymerizationNo information available.Hazardous ReactionsNone under normal processing.

10.4. Conditions to avoid

Incompatible products. Excess heat.

10.5. Incompatible materials

Oxidizing agent.

10.6. Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>). Nitrogen oxides (NOx). Sulfur oxides.

# **SECTION 11: TOXICOLOGICAL INFORMATION**

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

#### **Product Information**

(a) acute toxicity;

Oral Based on available data, the classification criteria are not met

DermalNo data availableInhalationNo data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Amoxicillin trihydrate	LD50 > 15 g/kg (Rat)	-	-

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory Category 1 Skin Category 1

May cause sensitization by skin contact

(e) germ cell mutagenicity; No data available

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(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(q) reproductive toxicity; No data available

No data available (h) STOT-single exposure;

No data available (i) STOT-repeated exposure;

No information available. **Target Organs** 

(j) aspiration hazard; Not applicable

Solid

delayed

Symptoms / effects, both acute and Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing.

11.2. Information on other hazards

Assess endocrine disrupting properties for human health. This product does not contain any **Endocrine Disrupting Properties** 

known or suspected endocrine disruptors.

# **SECTION 12: ECOLOGICAL INFORMATION**

12.1. Toxicity

Contains no substances known to be hazardous to the environment or that are not **Ecotoxicity effects** 

degradable in waste water treatment plants.

12.2. Persistence and degradability No information available

No information available 12.3. Bioaccumulative potential

12.4. Mobility in soil No information available

assessment

Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent

and very bioaccumulative (vPvB).

12.6. Endocrine disrupting

12.5. Results of PBT and vPvB

properties

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

**Persistent Organic Pollutant** This product does not contain any known or suspected substance **Ozone Depletion Potential** This product does not contain any known or suspected substance

# **SECTION 13: DISPOSAL CONSIDERATIONS**

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13.1. Waste treatment methods

Waste from Residues/Unused

**Products** 

Waste is classified as hazardous. Dispose of in accordance with the European Directives

on waste and hazardous waste. Dispose of in accordance with local regulations.

Contaminated Packaging Dispose of this container to hazardous or special waste collection point.

European Waste Catalogue (EWC) According to the European Waste Catalog, Waste Codes are not product specific, but

application specific.

Other Information Waste codes should be assigned by the user based on the application for which the product

was used. Do not empty into drains.

## **SECTION 14: TRANSPORT INFORMATION**

IMDG/IMO Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

<u>IATA</u> Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

**14.5. Environmental hazards** No hazards identified

**14.6. Special precautions for user** No special precautions required.

14.7. Maritime transport in bulk

according to IMO instruments

Not applicable, packaged goods

# **SECTION 15: REGULATORY INFORMATION**

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

#### **International Inventories**

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
Amoxicillin trihydrate	61336-70-7	-	-	-	-	X	-	-	Х
Component	CAS No	TSCA	TSCA Ir	ventory	DSL	NDSL	AICS	NZIoC	PICCS
•				ation -					1

**Active-Inactive** 

#### Amoxicillin trihydrate

Amoxicillin trihydrate 61336-70-7 - - X X X

Legend: X - Listed '-' - Not Listed	<b>KECL</b> - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

Authorisation/Restrictions according to EU REACH

Not applicable

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ſ	Component	CAS No	REACH (1907/2006) -	REACH (1907/2006) -	REACH Regulation (EC
			Annex XIV - Substances	Annex XVII - Restrictions	1907/2006) article 59 -
			Subject to Authorization	on Certain Dangerous	Candidate List of
			_	Substances	Substances of Very High
L					Concern (SVHC)
Γ	Amoxicillin trihydrate	61336-70-7	-	-	-

#### Seveso III Directive (2012/18/EC)

Component	CAS No	Seveso III Directive (2012/18/EC) -	Seveso III Directive (2012/18/EC) -	
		Qualifying Quantities for Major Accident	Qualifying Quantities for Safety Report	
		Notification	Requirements	
Amoxicillin trihydrate	61336-70-7	Not applicable	Not applicable	

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

#### **National Regulations**

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

**WGK Classification** Water endangering class = 2 (self classification)

#### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

# **SECTION 16: OTHER INFORMATION**

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

H317 - May cause an allergic skin reaction

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

Legend

CAS - Chemical Abstracts Service

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical **DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

Substances List

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**ENCS** - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances

IARC - International Agency for Research on Cancer

ICAO/IATA - International Civil Aviation Organization/International Air

MARPOL - International Convention for the Prevention of Pollution from

NZIoC - New Zealand Inventory of Chemicals

Predicted No Effect Concentration (PNEC)

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

EC50 - Effective Concentration 50%

TWA - Time Weighted Average

LD50 - Lethal Dose 50%

**Transport Association** 

ATE - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

PICCS - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

WEL - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

ADR - European Agreement Concerning the International Carriage of

Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime

Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

**Training Advice** 

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and

hygiene.

Prepared By Health, Safety and Environmental Department

Revision Date 24-Feb-2024

**Revision Summary** New emergency telephone response service provider.

# This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended.

#### **Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

# **End of Safety Data Sheet**