according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Amoxicillin Trihydrate / Potassium Clavulanate Formulation

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

1.1 Product identifier

Trade name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

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

Use of the Sub-Pharmaceutical

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company **MSD** 

Kilsheelan

Clonmel Tipperary, IE

Telephone 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

### Classification (REGULATION (EC) No 1272/2008)

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or

> breathing difficulties if inhaled. H400: Very toxic to aquatic life.

Short-term (acute) aguatic hazard, Cate-

gory 1

Long-term (chronic) aquatic hazard, Category 2

H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



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Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breath-

ing difficulties if inhaled.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P273 Avoid release to the environment.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

P391 Collect spillage.

#### Hazardous components which must be listed on the label:

Amoxicillin Trihydrate

#### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2.4689 %

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	Resp. Sens. 1A; H334 Aquatic Acute 1; H400 Aquatic Chronic 1;	>= 10 - < 20

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		M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 Acute toxicity estimate	>= 1 - < 10
		Acute oral toxicity: 1,620 mg/kg	

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

General advice In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

Protection of first-aiders First Aid responders should pay attention to self-protection,

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled If inhaled, remove to fresh air.

If not breathing, give artificial respiration.

If breathing is difficult, give oxygen.

Get medical attention.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

In case of eye contact Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

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

Risks May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

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Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

**SECTION 5: Firefighting measures** 

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

**SECTION 6: Accidental release measures** 

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

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Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

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

Methods for cleaning up : Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Avoid breathing mist or vapours.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Already sensitised individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-

tory irritants or sensitisers.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-

nated clothing before re-use.

The effective operation of a facility should include review of

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

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

Requirements for storage areas and containers

: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Gases

7.3 Specific end use(s)

Specific use(s) : No data available

# **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Amoxicillin Trihy- drate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal
	Further information: RSEN			
Aluminum tri- stearate	637-12-7	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day

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	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day
Glycerides, mixed decanoyl and octanoyl	Workers	Inhalation	Long-term systemic effects	177.79 mg/m3
	Workers	Skin contact	Long-term systemic effects	25.21 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	43.84 mg/m3
	Consumers	Skin contact	Long-term systemic effects	12.61 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12.61 mg/kg bw/day

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg
	Soil	0.456 mg/kg
Glycerides, mixed decanoyl and octanoyl	Oral (Secondary Poisoning)	0.03 mg/kg food

# 8.2 Exposure controls

#### **Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

#### Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387

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Filter type : Combined particulates and organic vapour type (A-P)

# **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Physical state : suspension

Colour : cream

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : Not applicable

Relative density : No data available

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Density : 0.900 - 1.100 g/cm<sup>3</sup>

Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

#### **SECTION 11: Toxicological information**

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

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

#### **Acute toxicity**

Not classified based on available information.

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**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

**Components:** 

**Amoxicillin Trihydrate:** 

Acute oral toxicity : LD50 (Rat): > 8,000 mg/kg

LD50 (Mouse): > 10,000 mg/kg

LD50 (Dog): > 3,000 mg/kg

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Skin corrosion/irritation

Not classified based on available information.

Components:

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

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#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

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

#### **Components:**

#### **Amoxicillin Trihydrate:**

Result : Sensitiser

Remarks : May cause sensitisation by inhalation.

largely based on human evidence

#### Benzyl alcohol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### **Amoxicillin Trihydrate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse Result: negative

#### Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

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#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

#### Reproductive toxicity

Not classified based on available information.

#### **Components:**

#### **Amoxicillin Trihydrate:**

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 200 mg/kg body weight

Result: Reduced fertility

Remarks: Not classified due to inconclusive data.

Test Type: Fertility Species: Rat

Application Route: Oral

Fertility: LOAEL: 500 mg/kg body weight

Result: Reduced fertility

Remarks: Not classified due to inconclusive data.

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: >= 1,000 mg/kg body weight

Result: No embryo-foetal toxicity

Test Type: Development

Species: Mouse Application Route: Oral

Developmental Toxicity: LOAEL: 200 mg/kg body weight Result: Some evidence of adverse effects on development,

based on animal experiments.

Remarks: Not classified due to inconclusive data.

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 200 mg/kg body weight Result: Reduced embryonic survival, Reduced offspring

weight gain

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Remarks: Not classified due to inconclusive data.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop: Test Type: Embryo-foetal development

ment Species: Mouse

**Application Route: Ingestion** 

Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

**Components:** 

**Amoxicillin Trihydrate:** 

Remarks : Not classified due to inconclusive data.

Repeated dose toxicity

**Components:** 

Amoxicillin Trihydrate:

Species : Rat
Application Route : Oral
Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Species : Dog
Application Route : Oral
Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Benzyl alcohol:

Species : Rat NOAEL : 1.072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

**Aspiration toxicity** 

Not classified based on available information.

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#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### **Experience with human exposure**

#### **Components:**

#### Amoxicillin Trihydrate:

Ingestion : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea,

flatulence, skin rash, Breathing difficulties Remarks: May produce an allergic reaction.

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

### Components:

### **Amoxicillin Trihydrate:**

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 0.035 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to algae/aquatic

plants

: NOEC (green algae): 530 mg/l

Exposure time: 72 h

EC50 (Synechococcus leopoliensis (blue-green algae)):

0.0022 mg/l

Exposure time: 96 h

NOEC (blue-green algae): 0.0057 mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox- :

icity)

100

M-Factor (Chronic aquatic

toxicity)

: 1

#### Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

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Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC: 51 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

#### 12.2 Persistence and degradability

#### **Components:**

**Amoxicillin Trihydrate:** 

Biodegradability Result: Readily biodegradable.

> Biodegradation: 88 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Benzyl alcohol:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 92 - 96 % Exposure time: 14 d

12.3 Bioaccumulative potential

**Components:** 

**Amoxicillin Trihydrate:** 

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: nlog Pow: -0.124

Method: OECD Test Guideline 107 octanol/water

Benzyl alcohol:

Partition coefficient: n-

octanol/water

: log Pow: 1.05

12.4 Mobility in soil

No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

#### **Components:**

#### Amoxicillin Trihydrate:

Assessment : Substance is not persistent, bioaccumulative, and toxic

(PBT).. Product does not contain substances which are very persistent and very bioaccumulative (vPvB) at levels of 0.1%

or higher.

#### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available

#### **SECTION 13: Disposal considerations**

# 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADN : UN 3082 ADR : UN 3082 RID : UN 3082

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IMDG : UN 3082 IATA : UN 3082

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Amoxicillin Trihydrate)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Amoxicillin Trihydrate)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Amoxicillin Trihydrate)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Amoxicillin Trihydrate)

**IATA** : Environmentally hazardous substance, liquid, n.o.s.

(Amoxicillin Trihydrate)

14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

#### 14.4 Packing group

ADN

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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**IMDG** 

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

**ADR** 

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

#### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances,

Conditions of restriction for the following entries should be considered:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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mixtures and articles (Annex XVII)

Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation

(Annex XIV)

E1

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

ENVIRONMENTAL

HAZARDS

Quantity 1

Quantity 2

100 t 200 t

#### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

# 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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#### **Full text of H-Statements**

H302 : Harmful if swallowed.

H319 : Causes serious eve irritation.

H332 : Harmful if inhaled.

H334 : May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Resp. Sens. : Respiratory sensitisation

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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- Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sources of key data used to

compile the Safety Data Sheet Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

#### Classification of the mixture: Classification procedure:

Resp. Sens. 1 H334 Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 2 H411 Calculation method

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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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IE / EN