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



Amoxicillin Trihydrate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 5750755-00011 Date of first issue: 27.04.2020

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

1.1 Product identifier

Trade name : Amoxicillin Trihydrate Formulation

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

Use of the Sub-

stance/Mixture

: Veterinary product

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.

Short-term (acute) aquatic hazard, Cate-

gory 1

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word : Danger

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

Hazard statements : H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P261 Avoid breathing dust.

P273 Avoid release to the environment. P284 Wear respiratory protection.

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

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.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Amoxicillin Trihydrate	61336-70-7	Resp. Sens. 1A;	>= 70 - < 90
		H334	
		Aquatic Acute 1;	
		H400	
		Aquatic Chronic 1;	
		H410	

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



Amoxicillin Trihydrate Formulation

Version 3.1	Revision Date: 30.09.2023	SDS Number: 5750755-00011	Date of last issue: 04.04.2023 Date of first issue: 27.04.2020	
			M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	

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.

Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

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.

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

tive airways dysfunction syndrome).

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

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

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

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.

Prevent further leakage or spillage if safe to do so. 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 : Surround spill with absorbents and place a damp covering

over the area to minimise entry of the material into the air.

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

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 determine 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 : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Avoid breathing dust.

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.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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 engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures,

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

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

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

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

dust)

Basis: IE OEL

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			

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

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 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : white to off-white

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) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 4.5 - 6.5

(as aqueous solution)

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : 0.3125 g/l partly soluble

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

Partition coefficient: n-

octanol/water

: Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

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 : Not applicable

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 : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

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.

Components:

Amoxicillin Trihydrate:

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

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

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

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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

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

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

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

Species: Mouse Result: negative

Carcinogenicity

Not classified based on available information.

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

Remarks: Not classified due to inconclusive data.

STOT - single exposure

Not classified based on available information.

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

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

Aspiration toxicity

Not classified based on available information.

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.

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



Amoxicillin Trihydrate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 30.09.2023 5750755-00011 Date of first issue: 27.04.2020 3.1

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

12.2 Persistence and degradability

Components:

Amoxicillin Trihydrate:

Biodegradability Result: Readily biodegradable.

Biodegradation: 88 % Exposure time: 28 d

Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Components:

Amoxicillin Trihydrate:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-

: log Pow: -0.124

octanol/water Method: OECD Test Guideline 107

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

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 : This substance is not considered to be persistent, bioaccumu-

lating and toxic (PBT).. This mixture contains no substance considered to be very persistent and very bioaccumulating

(vPvB).

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 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

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



Amoxicillin Trihydrate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 5750755-00011 Date of first issue: 27.04.2020

ADN ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Amoxicillin Trihydrate)

ADR ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Amoxicillin Trihydrate)

RID ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Amoxicillin Trihydrate)

IMDG ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Amoxicillin Trihydrate)

Environmentally hazardous substance, solid, n.o.s. **IATA**

(Amoxicillin Trihydrate)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN 9 **ADR** 9 RID 9 **IMDG** 9 9

IATA

14.4 Packing group

ADN

Packing group Ш Classification Code M7 Hazard Identification Number: 90 Labels 9

ADR

Packing group Ш Classification Code M7 Hazard Identification Number : 90 Labels 9 Tunnel restriction code (-)

RID

Packing group Ш Classification Code M7 Hazard Identification Number : 90 Labels

IMDG

Packing group Ш Labels 9

EmS Code F-A, S-F

IATA (Cargo)

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



Amoxicillin Trihydrate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 5750755-00011 Date of first issue: 27.04.2020

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

Packing instruction (LQ) : Y956
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

: Not applicable

Not applicable

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High :

Concern for Authorisation (Article 59).

Regulation (EC) No 1005/2009 on substances that de- : Not applicable

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

Regulation (EC) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

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

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

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.

Full text of H-Statements

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

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

Resp. Sens. : Respiratory sensitisation

IE OEL : List of Chemical Agents and Carcinogens with Occupational

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 -

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



Amoxicillin Trihydrate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 5750755-00011
 Date of first issue: 27.04.2020

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 - 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 1 H410 Calculation method

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