

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

### 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 Substance/Mixture : Veterinary product

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

Company : MSD  
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A  
Çubuk Yolu 2. Km  
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

National Poison Control Center (UZEM): 114  
Emergency: 1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification T.R. SEA No 28848

Respiratory sensitisation, Category 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Short-term (acute) aquatic hazard, Category 1

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Category 1

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

#### 2.2 Label elements

##### Labelling T.R. SEA No 28848

Hazard pictograms :



Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

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 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.  
P391 Collect spillage.

Hazardous components which must be listed on the label:

Amoxicillin Trihydrate

### 2.3 Other hazards

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. 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; H410  M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	>= 70 - < 90

For explanation of abbreviations see section 16.

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

### 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 advice immediately.<br>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.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention.                     |
| In case of skin contact    | : | Wash with water and soap.<br>Get medical attention if symptoms occur.   |
| In case of eye contact     | : | If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>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 difficulties if inhaled.<br><br>Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).<br>Contact with dust can cause mechanical irritation or drying of the skin.<br>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. |
|-----------|---|---|

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- |                              |   |  |
|------------------------------|---|--|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
|------------------------------|---|--|

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

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 products : 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 methods : Use extinguishing measures that are appropriate to local circumstances 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 protective 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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
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.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

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.<br>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.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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 contaminated clothing before re-use.<br>The effective operation of a facility should include review of 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.<br>Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents   |

### 7.3 Specific end use(s)

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

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 Trihydrate	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 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 143
Filter type	:	Particulates type (P)

### SECTION 9: Physical and chemical properties

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

Appearance	:	powder
Colour	:	white to off-white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	4,5 - 6,5
Melting point/freezing point	:	No data available

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	0,3125 g/l partly soluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids)	:	Not applicable
Molecular weight	:	No data available
Particle size	:	No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling 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.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
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.



# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

### 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
	:	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 development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: $\geq 1.000$ mg/kg body weight Result: No embryo-foetal toxicity

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

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.

### 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.

### Experience with human exposure

### Components:

#### Amoxicillin Trihydrate:

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

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

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 toxicity)	:	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-octanol/water	:	log Pow: -0,124 Method: OECD Test Guideline 107

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Components:

#### **Amoxicillin Trihydrate:**

Assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT).. This mixture contains no substance considered to be very persistent and very bioaccumulating (vPvB)..

### 12.6 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.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14: Transport information

### 14.1 UN number

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

### 14.2 UN proper shipping name

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.

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

(Amoxicillin Trihydrate)

**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Amoxicillin Trihydrate)

**IATA** : Environmentally hazardous substance, solid, n.o.s.  
(Amoxicillin Trihydrate)

### 14.3 Transport hazard class(es)

**ADN** : 9

**ADR** : 9

**RID** : 9

**IMDG** : 9

**IATA** : 9

### 14.4 Packing group

**ADN**

Packing group : III

Classification Code : M7

Hazard Identification Number : 90

Labels : 9

**ADR**

Packing group : III

Classification Code : M7

Hazard Identification Number : 90

Labels : 9

Tunnel restriction code : (-)

**RID**

Packing group : III

Classification Code : M7

Hazard Identification Number : 90

Labels : 9

**IMDG**

Packing group : III

Labels : 9

EmS Code : F-A, S-F

**IATA (Cargo)**

Packing instruction (cargo aircraft) : 956

Packing instruction (LQ) : Y956

Packing group : III

Labels : Miscellaneous

**IATA (Passenger)**

Packing instruction (passenger aircraft) : 956

Packing instruction (LQ) : Y956

Packing group : III

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

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

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable

Regulation on Persistent Organic Pollutants (Number 30595) : Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
----	-----------------------	---------------------	---------------------

#### Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".  
Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.  
Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

## 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.

The SDS has been prepared by: Name: Gökhan Ardiç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

### Full text of H-Statements

H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

**The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.**

### Full text of other abbreviations

Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Resp. Sens.	:	Respiratory sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 29.05.2020
1.2	05.01.2021	5933466-00003	Date of first issue: 20.05.2020

fied; 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; 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 Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Resp. Sens. 1	H334
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
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.

TR / EN