

THE UNITED LABORATORIES (INNER MONGOLIA) CO., LTD.

地址: 内蒙古巴彦淖尔经济技术开发区

聯邦制藥 (内蒙古) ADD: Bayannaoer Economy & Technology Park, Inner Mongolia, P. R. China

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# Amoxicillin Trihydrate

# 1 Chemicals and Company Identification

#### 1.1 Product identifier

Chinese Name of Product	阿莫西林
English Name of Product	Amoxicillin Trihydrate
Product Code	
Another name	Amoxicillin Trihydrate
CAS NO.	61336-70-7
EC NO.	2480038
Molecular Formula	C <sub>16</sub> H <sub>19</sub> N <sub>3</sub> O <sub>5</sub> S • 3H <sub>2</sub> O

# 1.2 Product recommended and restricted usage

Recommended usage of product	Consulting manufacturer	
Restricted Usage of product	Consulting manufacturer	

# 1.3 Emergency telephone number

# **Description of Hazardous**

# 2.1 Emergency overview

It may give rise to skin allergy; if inhale, it will give rise to allergy or difficulties in breathing

# 2.2 GHS hazardous category

Skin corrosion/irritation	Class 1
Eye injures/ Eye irritation	
STOT-single exposure	
Respiratory allergens	Class 1

# 2.3 GHS label element

Pictogram		
Signal word	Dangerous	

### 2.4 Hazardous statement

H317	It may give rise to skin allergy
H334	If inhale, it will give rise to allergy or asthma or difficulties in breathing.

#### 2.5 Precaution statement

# Prevention measure

~,	
P101	If required medical attention, carry product containers or labels.
P102	Kept out of children's reach.
P103	Read the label before use



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#### b) Response measure

10.50	
P261	Avoid inhalation of dust, flue gas, gas, smog, steam and spray.
P285	Wear respirators when ventilation is poor.
P270	Do not eat, drink or smoke when using this product
P304+P341	If inhale and breathe is difficult, transfer the patient to a place with fresh air, rest, and maintain a breathing position
P342+P311	If with respiratory symptoms, call the POISON CENTER or doctor.

#### c) Safe storage

P403+P233	Store in a well-ventilated place and keep in an airtight container.

#### d) Waste disposal

P501	Dispose of	contents/containers	in	accordance	with	local	1	regional	1	national	1
P301	internationa	l regulations.									

# Hazard Description

Eye

# Physical and chemical hazards

> Health haz	ard
Inhalation	Inhalation may cause allergy or asthma symptoms or breathing difficulties
Ingestion	May cause allergic reactions
Skin contact	May cause skin allergy

No information available

May cause allergic reactions

# **Environment hazard**

1	No information available

# Component Information

Components	Cas No.	EC No.	Assay ( Quantity Score, %)
Amoxicillin	61336-70-7		100%
Trihydrate			

# 4 First-aid Measures

# Description of first- aid measures

General advice	Remove contaminated clothing and seek immediate medical attention if severe allergic reaction occurs. If not breathing, artificial respiration should be performed. If breathing is difficult, give oxygen and seek medical attention.
F 1 1	Immediately raise your eyelids and flush eyes with water or saline. If you
Eye contact	feel uncomfortable, seek medical advice.
Skin contact	If the contacts cause physical discomfort through skin contact, they can use appropriate personnel protective equipment and remove contaminated clothing instantly and wash skin with soap and copious amounts of water. If it causes skin rash and eruptions, seek medical attention.
Ingestion	Gargle mouth with water and seek immediate medical attention. Do not feed the unconscious person anything from his mouth.



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Inhalation	Escaped from spot to the air place, maintains the respiratory tract is unobstructed. If breathing is difficult, give oxygen. If not breathing and heartbeat is stopped, give CPR. Seek medical attention
Protection for first-aid personnel	Transfer the patient to a safe place and consult the doctor. And show this MSDS to the doctor on-site.

# **★** Counsel for the protection of rescuer

1	Transfer the patient to a safe place
2	Consult the doctor and show this MSDS to the doctor on-site.
3	Avoid contact with skin and eyes
4	Use protective equipment, including breathing masks

# Special notice for doctors

Symptomatic treatment should be cond	ucted
Symptoms may be delayed	

# 5 Fire-fighting Measures

# Extinguishing media

Suitable extinguishing media	Firemen must wear full bunker clothing and breathing apparatus, fighting from the upper side of wind. Put out the flame with spray water, alcohol-resistant foam, dry powder or carbon dioxide. Water is recommended for fire extinguishing of packaged materials.
Unsuitable extinguishing media	

# ♣ Special hazard from this substance or its mixture

	1,71.	
1	No information available	

# Fire extinguishing precaution and protection measures

4	When extinguish fire, should wear respiratory mask (require or equivalent to the requirement of		
1	MSHA/NIOSH) and protective whole body suit.		
2	Move the container from the fire to an open area if possible		
_	Containers in a fire must be evacuated immediately if they are discolored or sound from a safety		
3	pressure relief device		
	Segregate the site of accident, prohibit irrelevant personnel access. Accept and dispose of fire		
4	fighting water to prevent environment pollution.		

# 6 Leakage Emergency Disposals

# Operation personal protection measures, protection equipment and emergency procedures

1	Use personal protective equipment
2	Prevent the formation of dust and inhalation of steam, vapor or gas
3	Ensure adequate ventilation.
4	Evacuate personnel to a safe area to avoid inhaling dust and to keep products out of the sewer
	D 0



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Collect and dispose of spills without dusting and shoveling them away, and kept in a properly sealed disposal container

# Environment precautions

Avoid discharge into waterways, sewers, surface drainage system or poor ventilation area. If spills are outdoors, cover with plastic sheets to minimize diffusion or contact with rainwater.

### Method and material for containment and cleaning up of leakage chemicals

Collect and place in appropriate labeled containers for recycling or disposal. Then remove the spillage, only in the case of waste water exists, flush the spillage area with a large amount of water directly to the on-site waste water treatment system.

# 7 Handling and Storage

# Precautions for safe handling

1	Avoid contact with skin and eyes
2	Prevent the formation of dust and aerosol
3	Provide suitable exhaust equipment where dust is generated
4	General fire protection measures

# Precautions for storage

1	Preserve in a cool place
2	Preserve in a tightly closed container, store in dry and ventilated place away from light
3	Avoid contact with incompatible substances
4	Keep sealed or away from moisture and flammable areas
5	Avoid long-term storage at high temperature (above room temperature, about 20°C)

# 8 Exposure Controls and Personal Protection

# Control parameters

#### Occupational exposure limit values

Component	Source of criteria	Category	Limit value	Remark
Amoxicillin Trihydrate GBZ 2.1-2007	007.04.0007	PC-TWA	_	
	PC-STEL		<del>-</del>	

#### Biological limit values

P Biological limit values			
Biological limit values	No information available		

#### Monitoring method

	W NAME OF THE PROPERTY OF THE
1	EN14042
l.	Workplace air, procedural guidelines for assessing exposure to chemical or biological reagents
	GBZ/T 160.1~GBZ/T 160.81-2004
2	Determination of toxic substances in workplace air (series standard)

# Engineering control

1 Engineering control: Maintain good ventilation

# Personal protection equipment





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General requirements	
Eye protection	Wear chemical goggles (Conform to EU EN166 or US NIOSH standard)
Hands protection	Wear protective gloves, the gloves must be checked before use
Respiratory protection	
Skin and body protection	Wear standard protective clothes and safety shoes.
Other protection	Smoking, drinking and eating are prohibited in the workplace. Wash and
	dress after work to maintain good personal hygiene habits.

# 9 Physical and Chemical Properties

# Physical and chemical properties

Appearance and character	Almost white solid powder
Odor	No information available
Odor threshold	No information available
Н	No information available
Melting point/freezing point (°C)	135-136 (decompose)
Initial boiling point and boiling range (℃)	743℃
Flash point (closed up, ℃)	Not applicable
Evaporation rate	Not applicable
Flammability (solid or gas)	No information available
Upper/lower explosive limits [%(V/V)]	No information available
Vapor pressure (kpa)	Not applicable
Vapor density (air=1)	Not applicable
Relative density (water=1)	1.54g/cm <sup>3</sup>
Solubility (mg/l)	Not available
Partition coefficient: octanol/ water	No information available
Auto-ignition temperature (°C)	No information available
Decomposition temperature (℃)	No information available
Viscosity (mm²/s)	Not available

# Stability and Reactivity

# 

- Otability and readdivity		
Reactivity	No information available	
Chemical stability	Store and use at normal ambient temperature, the product is stable	
Possibility of hazardous reactions	No information available	
Conditions to avoid	Avoid direct sunlight, and avoid forming dust fog to cause heat release.	



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contacting	or diffusion. Protected from Heat and moisture	
Prohibited content Strong oxides, strong acids, strong bases.		
Hazardous decomposition	No information available	
products		

# **Toxicological Information**

# 

Acute toxicity	No information available
Acute toxicity	No information available

# 

ID	Cas No.	Component name	IARC	NTP
1	61336-70-7	Amoxicillin Trihydrate	Not listed	Not listed

# Other information

Trypsin (Component)		
Skin corrosion/irritation	No information available	
Serious eye damage/irritation	Direct contact with the eyes may cause slight irritation	
Skin sensitization	No irritation after direct contact	
Respiratory sensitization	No information available	
Reproductive toxicity	No information available	
STOT-single exposure	No information available	
STOT-repeated exposure	No information available	
Inhalation hazard	No information available	
Germ cell mutagenicity	No information available	
Additional hazard of reproductive toxicity	No information available	

# 12 Ecological Information

# 

Component	Cas No.	Fish	Crustacea	Alga/Aquatic plant
Amoxicillin	61336-70-7	No information	No information	No information available
Trihydrate		available	available	140 Illioinnation available

# Chronic aquatic toxicity

Chronic aquatic toxicity	No information available	

# Other information

Persistence and degradability	No information available
Bio-concentration or Bioaccumulative potential	No information available
Mobility in soil	No information available
Results of PBT and vPvB a ssessment	No information available

#### 13 **Waste Disposal**



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Waste chemicals	Collect for recycling or recovery, if possible. The recommended					
	treatment is incineration.					
	Dispose of material on site in a licensed chemical incinerator, if allowed					
	by the incinerator permit.					
	If no on-site incinerator is available, dispose of material in a licensed					
	commercial chemical incinerator.					
Contaminant pooksages	Return the containers to the manufacturer or dispose of in accordance					
Contaminant packages	with national and local regulations.					
Descrition for weater	Refer to relevant regulations in national and local before waste disposal.					
Precaution for wastes	Refer to section 8 for safety protection measures of disposal personnel.					

# **Transport Information**

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UN NO.	This product is not regulated as hazardous goods
UN correct transportation name	No information available
Main hazard category of transportation	This product is not regulated as hazardous goods
Minor hazard category of transportation	This product is not regulated as hazardous goods
Package category	This product is not regulated as hazardous goods
Ocean pollutant (Yes/No)	No
Package mark	N/A
Packing method	Packing according to manufacturer's recommendation, For example: open steel drum, ampoule inside and ordinary wooden box outside or screw mouth glass bottle, Glass bottle with iron lid, plastic bottle, metal drum (can) inside and ordinary wooden box outside, etc.
Transportation precaution	The packing should be complete at the time of shipment and the loading should be safe.  During transportation, make sure the containers does not leak, collapse, fall or damage.  Transportation vehicles should be equipped with corresponding types and quantities of firefighting equipment and leakage emergency treatment equipment.  Avoid exposure to the sun and rain during transportation.



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#### International chemicals list

Component	EINECS	TSCA	DSL	IECSC	NEIoC	PICCS	KECI	AICS
Amoxicillin	×	¥	×	×	×	×	×	×
Trihydrate	^	•	^	^				

[EINECS] European Inventory of Existing Commercial Chemical Substances.

[TSCA] Toxic Substances Control Act, The American chemical inventory.

[DSL] Domestic Substances List, The Canadian chemical inventory.

[IECSC] Inventory of existing chemical substances in China.

[NEIoC] New Zealand Existing Inventory of Chemicals

[PICCS] Philippine Inventory of Chemicals and Chemical Substances

[KECI] Korea Existing Chemicals Inventory

[AICS] Australian Inventory of Chemical Substances.

### China chemical management inventory

Component	Α	В	С	D	E	F	G	Н	
Amoxicillin Trihydrate	×	×	×	×	×	×	×	×	×

- [A] < Hazardous Chemicals Catalog (2015)>, Administration of Work Safety, announcement no. 5 in 2015.
- [B] <Key Environmental Management Hazardous Chemicals Catalog>, Environment and Protection Department Office, announcement no. 33 in 2014.
- [C] <China Strictly Restricted Import and Export Toxic Chemicals Catalog>, Environment and Protection Department, announcement no. 85 in 2013.
- [D] <Stupefacient and Psychotropic Drugs Catalog (2013 edition), FDA, announcement no. 230 in 2013.
- [E] <Special Supervision Hazardous Chemicals Catalog (batch 1 and 2)>, Administration of Work Safety, announcement no. 95 in 2011 and announcement no. 12 in 2013.
- [F] <China Import and Export Controlled ODS Catalog (batch 1 to 6), Environment and Protection Department, series announcements in 2000 and 2012.
- [G] <Explosive Hazardous Chemicals Catalog (2011 edition) >, Public Security Ministry, announcement on 25th, Nov. 2011.
- [H] <National Hazardous Wastes Catalog>, appendix A, Environment and Protection Department, announcement no. 1 in 2016.
- [I] < High Toxic Substances Catalog> Ministry of Health, announcement no. 142 in 2003.

# 16 Other Information

# Revision information

Establishment Date	2013/02	
Revision Date	2015/06	
Revision Date	2019/05	
Revision Date	2020/07	