

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 1.8      Revision Date: 2023/11/01      SDS Number: 8845224-00009      Date of last issue: 2023/09/30  
Date of first issue: 2021/07/13

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road  
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

**Appearance** : suspension  
**Colour** : cream  
**Odour** : No data available

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

#### GHS Classification

Respiratory sensitisation : Category 1

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

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- Hazard pictograms :
- Signal word : Danger
- Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H400 Very toxic to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**  
P261 Avoid breathing mist or vapours.  
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.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

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

### Environmental hazards

Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

### Additional Labelling

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

### Other hazards which do not result in classification

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	>= 10 -< 20

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Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate	61177-45-5	$\geq 1$ -< 10
Aluminum tristearate	637-12-7	$\geq 1$ -< 10
Benzyl alcohol	100-51-6	$\geq 1$ -< 10

### 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- 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.
- Most important symptoms and effects, both acute and delayed : May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
- 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).
- Notes to physician : Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Metal oxides  
Nitrogen oxides (NO<sub>x</sub>)
- Specific extinguishing meth- : Use extinguishing measures that are appropriate to local cir-

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ods 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.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
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.

Methods and materials for containment and 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 absorbent.  
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.

### 7. HANDLING AND STORAGE

#### 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 assessment

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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 respiratory irritants or sensitisers.  
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

### Storage

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

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Further information: RSEN				
Aluminum tristearate	637-12-7	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminium)	ACGIH

**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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-

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Filter type : Recommended guidelines, use respiratory protection.  
Eye/face protection : Combined particulates and organic vapour type  
: 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.  
Skin and body protection : Work uniform or laboratory coat.  
Hand protection :  
Material : Chemical-resistant gloves  
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.  
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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension  
Colour : cream  
Odour : No data available  
Odour Threshold : No data available  
pH : No data available  
Melting point/freezing point : No data available  
Initial boiling point and boiling range : No data available  
Flash point : No data available  
Evaporation rate : No data available  
Flammability (solid, gas) : Not applicable  
Flammability (liquids) : No data available  
Upper explosion limit / Upper flammability limit : No data available

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Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	0.900 - 1.100 g/cm <sup>3</sup>
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

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### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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### 11. TOXICOLOGICAL INFORMATION

Exposure routes	:	Inhalation Skin contact
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Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 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

#### **Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:**

Acute oral toxicity : LD50 (Mouse): 4,526 mg/kg

#### **Aluminum tristearate:**

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

#### **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



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### Skin corrosion/irritation

Not classified based on available information.

#### Components:

#### **Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

#### **Aluminum tristearate:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : Based on data from similar materials  
  
Result : No skin irritation

#### **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:

#### **Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

#### **Aluminum tristearate:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

#### **Benzyl alcohol:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

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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

##### Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

##### Aluminum tristearate:

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

##### 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

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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

### Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

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: Ingestion  
Result: negative

### Aluminum tristearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

### 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 development : 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

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Result: Reduced embryonic survival, Reduced offspring weight gain  
Remarks: Not classified due to inconclusive data.

### Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intravenous injection  
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intravenous injection  
Result: negative

### Aluminum tristearate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### 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 development : Test Type: Embryo-foetal development  
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.

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### 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

#### **Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:**

Species : Mouse  
NOAEL : 400 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

#### **Aluminum tristearate:**

Species : Rat  
NOAEL :  $\geq$  5,000 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

#### **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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### 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.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### 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

##### **Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 960 mg/l  
Exposure time: 96 h  
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,610 mg/l  
Exposure time: 48 h  
Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 17 mg/l  
Exposure time: 72 h  
Method: Directive 67/548/EEC, Annex V, C.3.

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ErC50 (Pseudokirchneriella subcapitata (green algae)): > 170 mg/l

Exposure time: 72 h

Method: Directive 67/548/EEC, Annex V, C.3.

Toxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

### Aluminum tristearate:

#### Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

### Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
Exposure time: 96 h

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 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### Persistence and degradability

#### Components:

#### Amoxicillin Trihydrate:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 88 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 1.8      Revision Date: 2023/11/01      SDS Number: 8845224-00009      Date of last issue: 2023/09/30  
Date of first issue: 2021/07/13

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### Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Biodegradability : Result: Inherently biodegradable.  
Biodegradation: 72 %  
Exposure time: 28 d

### Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

### Bioaccumulative potential

#### Components:

#### Amoxicillin Trihydrate:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.  
Partition coefficient: n-octanol/water : log Pow: -0.124  
Method: OECD Test Guideline 107

### Potassium [2R-(2 $\alpha$ ,3Z,5 $\alpha$ )]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Partition coefficient: n-octanol/water : log Pow: -5.8  
Remarks: Calculation

### Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

### Mobility in soil

No data available

### Other adverse effects

#### Components:

#### Amoxicillin Trihydrate:

Results of PBT and vPvB 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).

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
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### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

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.

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Amoxicillin Trihydrate)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

##### IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Amoxicillin Trihydrate)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

Environmentally hazardous : yes

##### IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Amoxicillin Trihydrate)

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Amoxicillin Trihydrate / Potassium Clavulanate Formulation

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### National Regulations

#### GB 6944/12268

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Amoxicillin Trihydrate)
Class	:	9
Packing group	:	III
Labels	:	9
Marine pollutant	:	no

#### 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.

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## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

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

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## 16. OTHER INFORMATION

Revision Date : 2023/11/01

#### 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/>

Date format : yyyy/mm/dd

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA	:	8-hour, time-weighted average

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# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Amoxicillin Trihydrate / Potassium Clavulanate Formulation

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AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; KECl - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

### Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information 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.

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