

# SAFETY DATA SHEET



## Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version  
10.0

Revision Date:  
2025/04/14

SDS Number:  
8845228-00014

Date of last issue: 2024/09/28  
Date of first issue: 2021/07/13

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

#### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.  
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.

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### Precautionary statements

#### : **Prevention:**

P261 Avoid breathing mist or vapours.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves.  
P284 Wear respiratory protection.

#### : **Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
P391 Collect spillage.

#### : **Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

### 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)	ENCS No.
Amoxicillin Trihydrate	61336-70-7	>= 10 - < 20	
Aluminum tristearate	637-12-7	>= 1 - < 10	2-625
Benzyl alcohol	100-51-6	>= 0.9091 - <= 1.1111	3-1011

## 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

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	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	: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
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	: Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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 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.

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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 : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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-

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tory irritants or sensitizers.

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

Avoidance of contact  
Hygiene measures

- : Oxidizing agents
- : 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.
- Contaminated work clothing should not be allowed out of the workplace.
- 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.

### Storage

Conditions for safe storage

- : Keep in properly labelled containers.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.

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

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal
Further information: RSEN				
Aluminum tristearate	637-12-7	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
		TWA (Respirable particulate matter)	1 mg/m3 (Aluminium)	ACGIH
Benzyl alcohol	100-51-6	OEL-C	25 mg/m3	JP OEL

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				JSOH
	Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.			

**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 recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Remarks : Impermeable protective gloves

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.

Skin and body protection : Work uniform or laboratory coat.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : suspension

Colour : cream

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Up- : No data available

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per flammability limit

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

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Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

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

**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): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

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Not classified based on available information.

**Components:****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:****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

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**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

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**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	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Species	:	Humans
Result	:	positive
Assessment	:	Probability or evidence of low to moderate skin sensitisation rate in humans

**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

**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

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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

**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

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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.

**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

**Aluminum tristearate:**

||| Species : Rat  
NOAEL : >= 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.

**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.

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### 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

###### **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

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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

**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

**Benzyl alcohol:**

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

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects****Components:****Amoxicillin Trihydrate:**

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).  
Product does not contain substances which are very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

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

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.

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### National Regulations

Refer to section 15 for specific national regulation.

### 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.

ERG Code : 171

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## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

##### Harmful Substances Prohibited from Manufacture

Not applicable

##### Harmful Substances Required Permission for Manufacture

Not applicable

##### Substances Prevented From Impairment of Health

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

Chemical name	Concentration (%)	Remarks
Benzyl alcohol	>=0.9091 - <=1.1111	-

#### Substances Subject to be Indicated Names

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

Chemical name	Remarks
Benzyl alcohol	-

#### Skin and Eye Damage Substances (ISHL MO Art. 594-2)

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Chemical name
1-benzyl alcohol

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

# SAFETY DATA SHEET



## Amoxicillin Trihydrate / Potassium Clavulanic Formulation

Version  
10.0

Revision Date:  
2025/04/14

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8845228-00014

Date of last issue: 2024/09/28  
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### Waste Disposal and Public Cleansing Law

Industrial waste

**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

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

### 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/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect

# SAFETY DATA SHEET



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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; TECI - 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

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.

JP / EN