

## Amoxicillin Trihydrate Paste Formulation

Version 4.0      Revision Date: 2022/10/01      SDS Number: 2373172-00013      Date of last issue: 2022/04/09  
Date of first issue: 2018/01/16

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Amoxicillin Trihydrate Paste Formulation

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

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

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

Recommended use : Veterinary product

Restrictions on use :  
Not applicable

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### 2. HAZARDS IDENTIFICATION



#### GHS classification of chemical product

Respiratory sensitisation : Category 1

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 3

#### GHS label elements

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.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P261 Avoid breathing vapours.  
P273 Avoid release to the environment.  
P284 Wear respiratory protection.

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**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.

**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	>= 0.25 - < 1	

**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

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

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**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.

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**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 vapours. Do not swallow.

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- Avoidance of contact : Avoid contact with eyes.  
 Hygiene measures : 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  
 : 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.  
 : 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.  
 : 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.  
 : 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

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Further information: RSEN				

- 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.

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**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  
Material : Chemical-resistant 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.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : paste

Colour : colourless, to, white

Odour : characteristic

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 classified as a flammability hazard

Flammability (liquids) : No data available

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

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

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Solubility(ies)  
Water solubility : slightly soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Density : No data available

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 : Not applicable

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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**

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

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### II

#### **Skin corrosion/irritation**

Not classified based on available information.

#### **Serious eye damage/eye irritation**

Not classified based on available information.

#### **Respiratory or skin sensitisation**

##### **Skin sensitisation**

Not classified based on available information.

##### **Respiratory sensitisation**

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

#### **Components:**

##### **Amoxicillin Trihydrate:**

Result	:	Sensitiser
Remarks	:	May cause sensitisation by inhalation. largely based on human evidence

#### **Germ cell mutagenicity**

Not classified based on available information.

#### **Components:**

##### **Amoxicillin Trihydrate:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative
		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.
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	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  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



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**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

**Persistence and degradability****Components:****Amoxicillin Trihydrate:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 88 % Exposure time: 28 d Method: OECD Test Guideline 301B
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**Bioaccumulative potential****Components:****Amoxicillin Trihydrate:**

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

**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 : 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).

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : 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

**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**

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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.

**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.

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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**

Not applicable

**Substances Subject to be Indicated Names**

Not applicable

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**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****Until March 31st, 2023**

Not applicable

**From April 1st, 2023**

|| 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 : Not classified as noxious liquid substance

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

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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****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**

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 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 Recom-

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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