

## Amoxicillin Trihydrate Paste Formulation

Version 1.5      Revision Date: 09/13/2019      SDS Number: 2373168-00006      Date of last issue: 07.02.2019  
Date of first issue: 16.01.2018

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### Section 1: Identification

Product name : Amoxicillin Trihydrate Paste Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Telefax : 908-735-1496

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

Recommended use : Veterinary product

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### Section 2: Hazard identification

#### GHS Classification

Respiratory sensitisation : Resp. Sens.1

#### GHS label elements

Hazard pictograms :



Signal word : Danger

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

Precautionary statements :

**Prevention:**  
P261 Avoid breathing mist or vapours.  
P285 In case of inadequate ventilation wear respiratory protection.

**Response:**  
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.

**Disposal:**  
P501 Dispose of contents/ container to an approved waste

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disposal plant.

### Other hazards which do not result in classification

None known.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	>= 0.1 -< 10

### Section 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.

### Section 5: Fire-fighting 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

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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.
Hazchem Code	:	3Z

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**Section 6: Accidental release measures**

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. 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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**Section 7: Handling and storage**

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Avoid inhalation of vapour or mist. 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 Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. Take care to prevent spills, waste and minimize release to the environment.

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- 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.
- 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

## Section 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				

- 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
- 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.

## Section 9: Physical and chemical properties

- Appearance : paste

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Colour : colourless, to, white

Odour : characteristic

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 classified as a flammability hazard

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : slightly soluble

Partition coefficient: n-octanol/water : Not applicable

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 : Not applicable

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### Section 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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### Section 11: Toxicological information

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Amoxicillin Trihydrate:

Acute oral toxicity : LD50 (Rat): > 8,000 mg/kg  
LD50 (Mouse): > 10,000 mg/kg  
LD50 (Dog): > 3,000 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

##### Respiratory sensitisation

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

#### Components:

##### Amoxicillin Trihydrate:

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

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**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****Amoxicillin Trihydrate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

Test Type: Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Amoxicillin Trihydrate:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 200 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.

Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 500 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.

Effects on foetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL:  $\geq$  1,000 mg/kg body weight  
Result: No embryo-foetal toxicity

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.

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Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Reduced embryonic survival, Reduced offspring weight gain  
Remarks: Not classified due to inconclusive data.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Components:****Amoxicillin Trihydrate:**

Remarks : Not classified due to inconclusive data.

**Repeated dose toxicity****Components:****Amoxicillin Trihydrate:**

Species : Rat  
Application Route : Oral  
Exposure time : 6 Months  
Remarks : No significant adverse effects were reported

Species : Dog  
Application Route : Oral  
Exposure time : 6 Months  
Remarks : No significant adverse effects were reported

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Amoxicillin Trihydrate:**

Ingestion : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, flatulence, skin rash, Breathing difficulties  
Remarks: May produce an allergic reaction.

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**Section 12: Ecological information****Ecotoxicity****Components:****Amoxicillin Trihydrate:**



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Toxicity to fish : LC50 (No species specified): 0.035 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): 630 mg/l  
Exposure time: 72 h

EC50 (Synechococcus leopoliensis (blue-green algae)):  
0.0022 mg/l  
Exposure time: 96 h

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

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

**Bioaccumulative potential****Components:****Amoxicillin Trihydrate:**

Partition coefficient: n-octanol/water : log Pow: -0.124

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**Section 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.

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**Section 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

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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**

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****NZS 5433**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
N.O.S.  
(Amoxicillin Trihydrate)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 3Z

**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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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

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### HSW Controls

Certified handler certificate not required.  
Tracking hazardous substance not required.  
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

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## Section 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/>

Date format : dd.mm.yyyy

### Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;

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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.

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