

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024 Date of first issue: 16.01.2018

Section 1: Identification

Product identifier : Amoxicillin Trihydrate Paste Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Respiratory sensitisation : Category 1
Short-term (acute) aquatic hazard : Category 1

GHS Label elements, including precautionary statements

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.

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

Response:

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 2373167-00019	Date of last issue: 28.09.2024 Date of first issue: 16.01.2018
----------------	------------------------------	------------------------------	---

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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	>= 0.25 -< 1

Section 4: First-aid measures

Description of necessary 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

Risks : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
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).

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024
Date of first issue: 16.01.2018

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Special protective actions for fire-fighters

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

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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

Environmental precautions

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

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 2373167-00019	Date of last issue: 28.09.2024 Date of first issue: 16.01.2018
----------------	------------------------------	------------------------------	---

Methods for cleaning up	<p>: Soak up with inert absorbent material.</p> <p>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.</p> <p>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.</p> <p>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</p>
-------------------------	---

Section 7: Handling and storage

Precautions for safe handling

Technical measures	<p>: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.</p>
Local/Total ventilation	<p>: If sufficient ventilation is unavailable, use with local exhaust ventilation.</p>
Advice on safe handling	<p>: Do not breathe vapours.</p> <p>Do not swallow.</p> <p>Avoid contact with eyes.</p> <p>Avoid prolonged or repeated contact with skin.</p> <p>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</p> <p>Keep container tightly closed.</p> <p>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.</p> <p>Take care to prevent spills, waste and minimize release to the environment.</p>
Hygiene measures	<p>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke.</p> <p>Wash contaminated clothing before re-use.</p> <p>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.</p>

Conditions for safe storage, including any incompatibilities

Conditions for safe storage	<p>: Keep in properly labelled containers.</p> <p>Keep tightly closed.</p> <p>Keep in a cool, well-ventilated place.</p> <p>Store in accordance with the particular national regulations.</p>
Materials to avoid	<p>: Do not store with the following product types:</p>

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024 Date of first issue: 16.01.2018

Strong oxidizing agents

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

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

Appropriate engineering control 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.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face 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 protection	: Work uniform or laboratory coat.
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

Section 9: Physical and chemical properties

Appearance	: paste
Colour	: colourless, to, white
Odour	: characteristic
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024
Date of first issue: 16.01.2018

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 characteristics	
Particle size	: Not applicable

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024
Date of first issue: 16.01.2018

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.

Section 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

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:**

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024
Date of first issue: 16.01.2018

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: >= 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

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024
Date of first issue: 16.01.2018

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.

Section 12: Ecological information

Toxicity

Components:

Amoxicillin Trihydrate:

||| Toxicity to fish : LC50 (Carassius auratus (goldfish)): 0.035 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024
Date of first issue: 16.01.2018

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
------------------	---	---

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

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

Mobility in soil

No data available

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.
------------------------------------	---	--

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024
Date of first issue: 16.01.2018

Section 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.

Section 14: Transport information

International Regulations

UNRTDG

UN number : UN 3082

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

Transport hazard class(es) : 9

Packing group : III

Labels : 9

Environmental hazards : yes

IATA-DGR

UN/ID No. : UN 3082

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

Transport hazard class(es) : 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)

Transport hazard class(es) : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 2373167-00019 Date of last issue: 28.09.2024
Date of first issue: 16.01.2018

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable

Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 14.04.2025

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD compile the Safety Data eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>
Sheet

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

Date format : dd.mm.yyyy

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 Organization for Standardization; LDx - Dose associated with x% response; OECD - Organization for Economic Co-operation and Development; OEL - Occupational Exposure Limit; PBT - Persistent, Bioaccumulative and Toxic; REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals; RfD - Reference Dose; RfG - Reference Guidance for Exposure Assessment; SDS - Safety Data Sheet; TSCA - Toxic Substances Control Act; UN - United Nations; WHO - World Health Organization.

SAFETY DATA SHEET



Amoxicillin Trihydrate Paste Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 2373167-00019	Date of last issue: 28.09.2024 Date of first issue: 16.01.2018
----------------	------------------------------	------------------------------	---

ganisation 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; 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.

SG / EN