

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version
7.0

Revision Date:
06/17/2025

SDS Number:
2373166-00021

Date of last issue: 04/14/2025
Date of first issue: 01/16/2018

SECTION 1. IDENTIFICATION

Product name : Amoxicillin Trihydrate Paste Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Respiratory sensitization : Category 1

Other hazards

None known.

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 vapors. P285 In case of inadequate ventilation wear respiratory protection. Response: P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a doctor. Disposal: P501 Dispose of contents and container to an approved waste disposal plant.

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Version 7.0 Revision Date: 06/17/2025 SDS Number: 2373166-00021 Date of last issue: 04/14/2025
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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Amoxicillin Trihydrate	61336-70-7*	>= 0.5 - <= 1.5	TSC

* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

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 : 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).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version 7.0	Revision Date: 06/17/2025	SDS Number: 2373166-00021	Date of last issue: 04/14/2025 Date of first issue: 01/16/2018
----------------	------------------------------	------------------------------	-------------------------------------------------------------------

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

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

- 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 breathe vapors.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.

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Amoxicillin Trihydrate Paste Formulation

Version 7.0	Revision Date: 06/17/2025	SDS Number: 2373166-00021	Date of last issue: 04/14/2025 Date of first issue: 01/16/2018
----------------	------------------------------	------------------------------	-------------------------------------------------------------------

	<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 sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.</p> <p>Take care to prevent spills, waste and minimize release to the environment.</p>
Conditions for safe storage	<p>: Keep in properly labeled 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> <p>Strong oxidizing agents</p> <p>Gases</p>

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

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				

Engineering measures	<p>: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).</p> <p>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</p> <p>Laboratory operations do not require special containment.</p>
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Personal protective equipment

Respiratory protection	<p>: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.</p>
Hand protection Material	<p>: Chemical-resistant gloves</p>
Eye protection	<p>: Wear safety glasses with side shields or goggles.</p>

SAFETY DATA SHEET

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Amoxicillin Trihydrate Paste Formulation

Version 7.0	Revision Date: 06/17/2025	SDS Number: 2373166-00021	Date of last issue: 04/14/2025 Date of first issue: 01/16/2018
----------------	------------------------------	------------------------------	-------------------------------------------------------------------

- 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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: paste
Color	: colorless, to, white
Odor	: characteristic
Odor 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
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version 7.0	Revision Date: 06/17/2025	SDS Number: 2373166-00021	Date of last issue: 04/14/2025 Date of first issue: 01/16/2018
----------------	------------------------------	------------------------------	-------------------------------------------------------------------

Density	: No data available
Solubility(ies)	
Water solubility	: slightly soluble
Partition coefficient: n-octanol/water	: Not applicable
Autoignition 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.
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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version
7.0

Revision Date:
06/17/2025

SDS Number:
2373166-00021

Date of last issue: 04/14/2025
Date of first issue: 01/16/2018



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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

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

Components:

Amoxicillin Trihydrate:



- | | | |
|---------|---|---------------------------------------------------------------------------|
| Result | : | Sensitizer |
| Remarks | : | May cause sensitization 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.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version
7.0

Revision Date:
06/17/2025

SDS Number:
2373166-00021

Date of last issue: 04/14/2025
Date of first issue: 01/16/2018

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 fetal development	: Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: >= 1,000 mg/kg body weight Result: No embryo-fetal 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.
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SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version
7.0

Revision Date:
06/17/2025

SDS Number:
2373166-00021

Date of last issue: 04/14/2025
Date of first issue: 01/16/2018

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, Diarrhea, flatulence, skin rash, Breathing difficulties
		Remarks: May produce an allergic reaction.

SECTION 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

Persistence and degradability

Components:

Amoxicillin Trihydrate:

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version 7.0 Revision Date: 06/17/2025 SDS Number: 2373166-00021 Date of last issue: 04/14/2025
Date of first issue: 01/16/2018

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.

SECTION 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.

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
Labels : 9
Environmentally hazardous : yes

IATA-DGR

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version 7.0	Revision Date: 06/17/2025	SDS Number: 2373166-00021	Date of last issue: 04/14/2025 Date of first issue: 01/16/2018
----------------	------------------------------	------------------------------	-------------------------------------------------------------------

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 IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Amoxicillin Trihydrate)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(Amoxicillin Trihydrate)
Remarks	:	Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version 7.0 Revision Date: 06/17/2025 SDS Number: 2373166-00021 Date of last issue: 04/14/2025
Date of first issue: 01/16/2018

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Glycerides, mixed decanoyl and octanoyl

73398-61-5

California Prop. 65

WARNING: This product can expose you to chemicals including tert-Butyl-4-methoxyphenol, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

SAFETY DATA SHEET

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Amoxicillin Trihydrate Paste Formulation

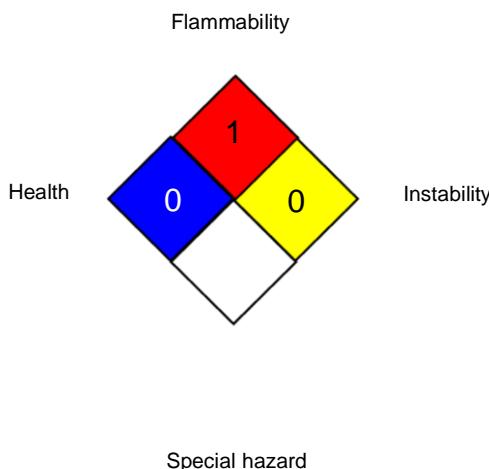
Version
7.0

Revision Date:
06/17/2025

SDS Number:
2373166-00021

Date of last issue: 04/14/2025
Date of first issue: 01/16/2018

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Amoxicillin Trihydrate Paste Formulation

Version 7.0	Revision Date: 06/17/2025	SDS Number: 2373166-00021	Date of last issue: 04/14/2025 Date of first issue: 01/16/2018
----------------	------------------------------	------------------------------	-------------------------------------------------------------------

(United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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

Revision Date : 06/17/2025

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

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.

US / Z8