

## Amoxicillin Trihydrate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
4.0	14.04.2025	5727316-00014	Date of first issue: 27.04.2020

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Amoxicillin Trihydrate Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD  
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@msd.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**

Respiratory sensitization : Category 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 dust.  
P284 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 POISON CENTER or doctor/ physician.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	>= 70 -< 90

**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.  
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
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).  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
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 (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion prod- : 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 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.  
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 : Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.  
Add excess liquid to allow the material to enter into solution.  
Soak up with inert absorbent material.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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 : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.

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- 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 sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.
- 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 labeled 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

## Ingredients 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 feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**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 : Particulates type
- Hand protection : Chemical-resistant gloves
- Material :

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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 : powder

Color : white to off-white

Odor : No data available

Odor Threshold : No data available

pH : 4.5 - 6.5  
(as aqueous solution)

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : 0.3125 g/l partly soluble

Partition coefficient: n-octanol/water : Not applicable

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Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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

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**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.

**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

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	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: $\geq$ 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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**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, Diarrhea, flatulence, skin rash, Breathing difficulties Remarks: May produce an allergic reaction.
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**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:**

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

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**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.
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**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 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

**IATA-DGR**

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Amoxicillin Trihydrate)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

**IMDG-Code**

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)
Class	:	9

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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.

**Domestic regulation****NOM-002-SCT**

UN number	: UN 3077
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)
Class	: 9
Packing group	: III
Labels	: 9

**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****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

**The ingredients 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
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

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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 Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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