according to GB/T 16483 and GB/T 17519



Amoxicillin Trihydrate Solid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 2024/07/06 2024/09/28 1161161-00020 5.0 Date of first issue: 2016/12/19

1. PRODUCT AND COMPANY IDENTIFICATION

Amoxicillin Trihydrate Solid Formulation Product name

Manufacturer or supplier's details

Company MSD

Address No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone +1-908-740-4000

Emergency telephone number: 86-571-87268110

E-mail address EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product Restrictions on use Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance powder Colour white

Odour characteristic

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Very toxic to aquatic life with long lasting effects.

GHS Classification

Respiratory sensitisation Category 1

Short-term (acute) aquatic

hazard

Long-term (chronic) aquatic

hazard

Category 1

Category 1

GHS label elements

Hazard pictograms



Signal word Danger

according to GB/T 16483 and GB/T 17519



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Hazard statements : H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P261 Avoid breathing dust.

P273 Avoid release to the environment. 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/ doctor. P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Physical and chemical hazards

Not classified based on available information.

Health hazards

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

Environmental hazards

Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

according to GB/T 16483 and GB/T 17519



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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, DO NOT induce vomiting.

Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

and effects, both acute and delayed

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

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.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

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-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

according to GB/T 16483 and GB/T 17519



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6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 minimise 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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

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

Advice on safe handling

Use only with adequate ventilation.

Do not breathe dust.

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 as-

sessment

Keep container tightly closed.

Already sensitised individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease,

according to GB/T 16483 and GB/T 17519



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should consult their physician regarding working with respira-

tory irritants or sensitisers.

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.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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/m3 (OEB 1)	Internal		
	Further inform	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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type

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 and body protection

Hand protection

Work uniform or laboratory coat.

Material : Chemical-resistant gloves

Hygiene measures : If exposure to chemical is likely during typical use, provide

according to GB/T 16483 and GB/T 17519



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eye flushing systems and safety showers close to the work-

ing 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white

Odour : characteristic

Odour Threshold : No data available

pH : 5.5 - 7.5

(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, han-

dling or other means.

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 : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

according to GB/T 16483 and GB/T 17519



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Water solubility 1.43 g/l

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Not explosive Explosive properties

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle characteristics

Particle size No data available

10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

Oxidizing agents

No hazardous decomposition products are known.

products

11. TOXICOLOGICAL INFORMATION

Exposure routes Inhalation

> Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Amoxicillin Trihydrate:

LD50 (Rat): > 8,000 mg/kg Acute oral toxicity

LD50 (Mouse): > 10,000 mg/kg

according to GB/T 16483 and GB/T 17519



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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:

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

according to GB/T 16483 and GB/T 17519



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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 develop-

ment

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 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:

according to GB/T 16483 and GB/T 17519



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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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Amoxicillin Trihydrate:

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 0.035 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to algae/aquatic

plants

NOEC (green algae): 530 mg/l

Exposure time: 72 h

EC50 (Synechococcus leopoliensis (blue-green algae)):

0.0022 mg/l

Exposure time: 96 h

NOEC (blue-green algae): 0.0057 mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox- : 100

icity)

M-Factor (Chronic aquatic

toxicity)

according to GB/T 16483 and GB/T 17519



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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- : log Pow: -0.124

octanol/water 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.

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

according to GB/T 16483 and GB/T 17519



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N.O.S.

(Amoxicillin Trihydrate)

Class 9 Packing group Ш 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 Ш

Labels Miscellaneous

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-

ger 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 Packing group Ш 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

GB 6944/12268

UN number **UN 3077**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Amoxicillin Trihydrate)

Class 9 Ш Packing group Labels 9 Marine pollutant no

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.

according to GB/T 16483 and GB/T 17519



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15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de-

termination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under : Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2024/09/28

Further information

Sources of key data used to compile the Safety Data

Sheet

a used to : Internal technical data, data from raw material SDSs, OECD Data eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

according to GB/T 16483 and GB/T 17519



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

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals: OECD - Organization for Economic Co-operation and Development: OPPTS - Office of Chemical Safety and Pollution Prevention: PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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

Disclaimer

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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