SAFETY DATA SHEET

Amoxicillin Trihydrate Solid Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Amoxicillin Trihydrate Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   20 Spartan Road
   1619 Spartan, South Africa
   Telephone : +27119239300
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   +1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Respiratory sensitisation, Category 1
   H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
   H400: Very toxic to aquatic life.
   Short-term (acute) aquatic hazard, Category 1
   H410: Very toxic to aquatic life with long lasting effects.
   Long-term (chronic) aquatic hazard, Category 1

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   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.
2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Trihydrate</td>
<td>61336-70-7</td>
<td></td>
<td></td>
<td></td>
<td>Resp. Sens. 1A; H334 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
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).

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.

4.2 Most important symptoms and effects, both acute and delayed

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

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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.
5.3 Advice for firefighters

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

6.1 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).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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: Use only with adequate ventilation.
Advice on safe handling: Avoid breathing 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-
essment.
Keep container tightly closed.
Already sensitised individuals should consult their physician
regarding working with respiratory 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.

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 contami-
nated 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Keep tightly closed.
Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types:
Strong oxidizing agents.

7.3 Specific end use(s)

Specific use(s): No data available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>
| Amoxicillin Trihy-
| drate              | 61336-70-7 | TWA                           | 1 mg/m3 (OEB 1)    | Internal |

Further information: RSEN
8.2 Exposure controls

**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**

- **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.

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

- **Skin and body 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: Particulates type (P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic 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, handling or other means.
- **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)
  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

Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
  Flammability (liquids) : No data available
  Molecular weight : No data available
  Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.

10.2 Chemical stability
  Stable under normal conditions.

10.3 Possibility of hazardous reactions
  Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
  Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
  No hazardous decomposition products are known.
SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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

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

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:

Amoxicillin Trihydrate:

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

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

Effects on foetal development:
- Test Type: Development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: \( \geq 1.000 \) mg/kg body weight
  - Result: No embryo-foetal toxicity

- Test Type: Development
  - Species: Mouse
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 200 mg/kg body weight
  - Result: Some evidence of adverse effects on development, based on animal experiments.
  - Remarks: Not classified due to inconclusive data.

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.
Components:

Amoxicillin Trihydrate:
Remarks : Not classified due to inconclusive data.

Repeated dose toxicity
Components:

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

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure
Components:

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

SECTION 12: Ecological information

12.1 Toxicity
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
SAFETY DATA SHEET

Amoxicillin Trihydrate Solid Formulation

12.2 Persistence and degradability

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

12.3 Bioaccumulative potential

Components:
Amoxicillin Trihydrate:
Bioaccumulation: Remarks: Bioaccumulation is unlikely.
Partition coefficient: n-octanol/water: log Pow: -0,124
   Method: OECD Test Guideline 107

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Components:
Amoxicillin Trihydrate:
Assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This mixture contains no substance considered to be very persistent and very bioaccumulating (vPvB).

12.6 Other adverse effects

Product:
Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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.

14.1 UN number

ADN: UN 3077
ADR: UN 3077
RID: UN 3077
IMDG: UN 3077
IATA: UN 3077

14.2 UN proper shipping name

ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)
IATA: Environmentally hazardous substance, solid, n.o.s. (Amoxicillin Trihydrate)

14.3 Transport hazard class(es)

ADN: 9
ADR: 9
RID: 9
IMDG: 9
IATA: 9

14.4 Packing group
| **ADN** |  
| Packing group | III  
| Classification Code | M7  
| Hazard Identification Number | 90  
| Labels | 9  
| **ADR** |  
| Packing group | III  
| Classification Code | M7  
| Hazard Identification Number | 90  
| Labels | 9  
| Tunnel restriction code | (-)  
| **RID** |  
| Packing group | III  
| Classification Code | M7  
| Hazard Identification Number | 90  
| Labels | 9  
| **IMDG** |  
| Packing group | III  
| Labels | 9  
| EmS Code | F-A, S-F  
| **IATA (Cargo)** |  
| Packing instruction (cargo aircraft) | 956  
| Packing instruction (LQ) | Y956  
| Packing group | III  
| Labels | Miscellaneous  
| **IATA (Passenger)** |  
| Packing instruction (passenger aircraft) | 956  
| Packing instruction (LQ) | Y956  
| Packing group | III  
| Labels | Miscellaneous  

**14.5 Environmental hazards**

| **ADN** |  
| Environmentally hazardous | yes  
| **ADR** |  
| Environmentally hazardous | yes  
| **RID** |  
| Environmentally hazardous | yes  
| **IMDG** |  
| Marine pollutant | yes  
| **IATA (Passenger)** |  
| Environmentally hazardous | yes  
| **IATA (Cargo)** |  
| Environmentally hazardous | yes  

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**SAFETY DATA SHEET**

Amoxicillin Trihydrate Solid Formulation

**Version**: 3.2  
**Revision Date**: 27.08.2021  
**SDS Number**: 1161184-00013  
**Date of last issue**: 09.04.2021  
**Date of first issue**: 19.12.2016

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**ADN**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**ADR**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**IMDG**
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

**14.5 Environmental hazards**

**ADN**
- Environmentally hazardous: yes

**ADR**
- Environmentally hazardous: yes

**RID**
- Environmentally hazardous: yes

**IMDG**
- Marine pollutant: yes

**IATA (Passenger)**
- Environmentally hazardous: yes

**IATA (Cargo)**
- Environmentally hazardous: yes
14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

- H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- Aquatic Acute: Short-term (acute) aquatic hazard
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Resp. Sens.: Respiratory sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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
Further information:


Classification of the mixture:

Resp. Sens. 1: H334
Aquatic Acute 1: H400
Aquatic Chronic 1: H410

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.

ZA / EN