Section 1: Identification

Product name: Amoxicillin Trihydrate Formulation

Manufacturer or supplier's details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

Section 2: Hazard identification

GHS Classification
Respiratory sensitisation: 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/doctor.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
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.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Trihydrate</td>
<td>61336-70-7</td>
<td>&gt;= 60 -&lt;= 100</td>
</tr>
</tbody>
</table>

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 : 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.

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

Hazchem Code: 2Z

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: 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.

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: 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 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 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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Trihydrate</td>
<td>61336-70-7</td>
<td>TWA</td>
<td>1 mg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information:</td>
<td>RSEN</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
Hand protection
Material
Chemical-resistant gloves
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.
SAFETY DATA SHEET

Amoxicillin Trihydrate Formulation

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
- **Colour**: white to off-white
- **Odour**: No data available
- **Odour 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
- **Vapour pressure**: Not applicable
- **Relative vapour 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
- **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.

### Molecular weight
- No data available

### 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

#### Exposure routes
- 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

Chronic toxicity

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: >= 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
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

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: 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
Section 13: Disposal considerations

Disposal methods
Waste from residues: 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

**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
- 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.

**National Regulations**

**NZS 5433**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET

Amoxicillin Trihydrate Formulation

Version 1.4  Revision Date: 27.08.2021  SDS Number: 5727318-00005  Date of last issue: 03.03.2021

N.O.S. (Amoxicillin Trihydrate)
Class: 9
Packing group: III
Labels: 9
Hazchem Code: 2Z

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

Section 16: Other information

Further information

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...
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.