SAFETY DATA SHEET

Amoxicillin Trihydrate Liquid Formulation

Section 1: Identification

Product name: Amoxicillin Trihydrate Liquid 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 mist or vapours.
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.
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Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amoxicillin Trihydrate</td>
<td>61336-70-7</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td></td>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>&lt; 10</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 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 : 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).

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.

Hazardous combustion products : Carbon oxides
Metal oxides

Specific extinguishing method : Use extinguishing measures that are appropriate to local cir-
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 dyking or other appropriate containment to keep material from spreading. If dyked 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: Use only with adequate ventilation.

Advice on safe handling: Avoid breathing mist or vapours. 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 assessment. Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. 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.

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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminium)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: RSEN

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

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

Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment:
Safety glasses

Skin and body protection: Skin should be washed after contact.

Section 9: Physical and chemical properties

Appearance: suspension

Colour: white
Odour : strong
Odour 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 applicable
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 : No data available
Relative vapour density : No data available
Relative density : No data available
Density : 0.99 - 1.10 g/l
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition 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 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

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

Fatty acids, C14-26, aluminum salts:
Acute oral toxicity: LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute inhalation toxicity: LC50 (Rat): > 5.15 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Fatty acids, C14-26, aluminum salts:
Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 431
Remarks: Based on data from similar materials
Result : No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Fatty acids, C14-26, aluminum salts:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

**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

**Fatty acids, C14-26, aluminum salts:**
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

**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

**Fatty acids, C14-26, aluminum salts:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

**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.

Fatty acids, C14-26, aluminum salts:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

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

Fatty acids, C14-26, aluminum salts:
Species: Rat
Application Route: Ingestion
Exposure time: 42 Days
Remarks: Based on data from similar materials
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

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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (green algae): 530 mg/l</th>
<th>EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0022 mg/l</th>
<th>NOEC (blue-green algae): 0.0057 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

Persistence and degradability

**Components:**

**Amoxicillin Trihydrate:**

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

**Fatty acids, C14-26, aluminum salts:**

Biodegradability: Result: Readily biodegradable.
- Biodegradation: 81.2%
- Exposure time: 28 d
- Method: OECD Test Guideline 301B
- Remarks: Based on data from similar materials
Bioaccumulative potential

**Components:**

**Amoxicillin Trihydrate:**
- **Bioaccumulation**: Remarks: Bioaccumulation is unlikely.
- **Partition coefficient: n-octanol/water**: log Pow: -0.124
  Method: OECD Test Guideline 107

**Fatty acids, C14-26, aluminum salts:**
- **Partition coefficient: n-octanol/water**: log Pow: > 7
  Remarks: Calculation

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 (vPvB).

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 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Amoxicillin Trihydrate)
- **Class**: 9
- **Packing group**: III
- **Labels**: 

**IATA-DGR**
- **UN/ID No.**: UN 3082
- **Proper shipping name**: Environmentally hazardous substance, liquid, n.o.s. (Amoxicillin Trihydrate)
- **Class**: 9
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Amoxicillin Trihydrate Liquid Formulation

| 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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Amoxicillin Trihydrate)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z

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:
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Amoxicillin Trihydrate Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 27.08.2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>27.08.2021</td>
<td>1198864-00010</td>
<td></td>
</tr>
</tbody>
</table>

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
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

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.

NZ / EN