SAFETY DATA SHEET

Amoxicillin Trihydrate Liquid Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Amoxicillin Trihydrate Liquid Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: 2000 Galloping Hill Road
          Kenilworth - New Jersey - U.S.A. 07033
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

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 mist or vapors.
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
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components
SAFETY DATA SHEET

Amoxicillin Trihydrate Liquid Formulation

Chemical name | CAS-No. | Concentration (% w/w)
--- | --- | ---
Amoxicillin Trihydrate | 61336-70-7 | >= 10 - < 20
Fatty acids, C14-26, aluminum salts | 97404-28-9 | >= 1 - < 5

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 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.
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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 diking or other appropriate containment to keep material from spreading. If diked 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 vapors.
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 sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers.
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 labeled containers.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
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Amoxicillin Trihydrate Liquid Formulation

**Version:** 3.1  
**Revision Date:** 27.08.2021  
**SDS Number:** 1198862-00011  
**Date of last issue:** 27.08.2020  
**Date of first issue:** 05.01.2017

Strong oxidizing agents

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients 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>Fatty acids, C14-26, aluminum salts</td>
<td>97404-28-9</td>
<td>VLE-PPT (Respirable fraction)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>NOM-010-STPS-2014</td>
</tr>
</tbody>
</table>

**Further information:** RSEN

**TWA** (Respirable particulate matter) 1 mg/m³ (Aluminum)  
**ACGIH**

**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:** VLE-PPT (Respirable fraction)
- **Hand protection:** Particulates type
- **Material:** Chemical-resistant gloves
- **Remarks:** Choose gloves to protect hands against chemicals depending on the concentration 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
- **Color:** white
- **Odor:** strong
- **Odor 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
Vapor pressure : No data available
Relative vapor 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
Autoignition 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.
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Conditions to avoid: None known.
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

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

Species: reconstructed human epidermis (RhE)
Method: OECD Test Guideline 439
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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Result</th>
<th>Sensitizer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>May cause sensitization by inhalation. largely based on human evidence</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 429</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Amoxicillin Trihydrate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Rodent dominant lethal test (germ cell) (in vivo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 471</td>
<td></td>
</tr>
</tbody>
</table>
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 fetal development  :  Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: >= 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.

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 fetal 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, Diarrhea, 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:**

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

**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.
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Date of last issue: 27.08.2020
Date of first issue: 05.01.2017

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: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Amoxicillin Trihydrate)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes
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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.

Domestic regulation

NOM-002-SCT
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Con-
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Revision Date: 27.08.2021

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.

MX / Z8