SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 1.3  Revision Date: 27.08.2021  SDS Number: 8845221-00002  Date of last issue: 13.07.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Manufacturer or supplier's details
Company: MSD
Address: Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
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: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Respiratory sensitization: Category 1
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements: Prevention:
P273 Avoid release to the environment.
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.

Additional Labeling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2,4689 %

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Trihydrate</td>
<td>61336-70-7</td>
<td>Respiratory sensitization, Sub-category 1A Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Potassium [2R-(2α,3Z,5α):3- (2-hydroxyethyldene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2- carboxylate</td>
<td>61177-45-5</td>
<td>Flammable solids, Category 2 Acute toxicity (Oral), Category 5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>Acute toxicity (Oral), Category 4 Acute toxicity (Inhalation), Category 4 Eye irritation, Category 2A</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td></td>
<td></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.
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<table>
<thead>
<tr>
<th>Version</th>
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</thead>
<tbody>
<tr>
<td>1.3</td>
<td>27.08.2021</td>
<td>8845221-00002</td>
<td>13.07.2021</td>
<td>13.07.2021</td>
</tr>
</tbody>
</table>

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 firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal oxides
Nitrogen oxides (NOx)

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.

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:
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></td>
<td></td>
<td></td>
<td>Further information: RSEN</td>
<td></td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>(Inhalable particulate matter)</th>
<th>TWA (Respirable particulate matter)</th>
<th>3 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>ACGIH</td>
<td></td>
</tr>
</tbody>
</table>

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: Combined particulates and organic vapor type

Hand protection: 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: cream
Odor: No data available
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 : Not applicable
Relative vapor density : No data available
Relative density : No data available
Density : 0,900 - 1,100 g/cm³
Solubility(ies) Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
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 : 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 : 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

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Product:

Acute oral toxicity:
- Acute toxicity estimate: > 5.000 mg/kg
  Method: Calculation method

Acute inhalation toxicity:
- Acute toxicity estimate: > 10 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:

Amoxicillin Trihydrate:
Acute oral toxicity:
- LD50 (Rat): > 8.000 mg/kg
- LD50 (Mouse): > 10.000 mg/kg
- LD50 (Dog): > 3.000 mg/kg

Potassium [2R-(2α,3Z,5α)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate):
Acute oral toxicity:
- LD50 (Mouse): 4.526 mg/kg

Aluminum tristearate:
Acute oral toxicity:
- LD50 (Rat, female): > 2.000 mg/kg
  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

Benzyl alcohol:
Acute oral toxicity:
- LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity:
- LC50 (Rat): > 4,178 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403
Skin corrosion/irritation
Not classified based on available information.

Components:

Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Aluminum tristearate:
Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439
Remarks : Based on data from similar materials
Result : No skin irritation

Benzyl alcohol:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

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

Components:

Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Aluminum tristearate:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Benzyl alcohol:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

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:
Result : Sensitizer
Remarks : May cause sensitization by inhalation. largely based on human evidence

Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:
Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Aluminum tristearate:
Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Benzyl alcohol:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

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
### Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylened)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Aluminum tristearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

### Carcinogenicity

Not classified based on available information.

### Components:

#### Benzyl alcohol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 451</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>
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.

Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:
Effects on fertility:
- Test Type: Fertility/early embryonic development
  Species: Rat
  Application Route: Intravenous injection
  Result: negative

Effects on fetal development:
- Test Type: Fertility/early embryonic development
  Species: Rat
  Application Route: Intravenous injection
  Result: negative
### Aluminum tristearate:

**Effects on fertility**
- Test Type: Two-generation reproduction toxicity study
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 416
- Result: negative
- Remarks: Based on data from similar materials

**Effects on fetal development**
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

### Benzyl alcohol:

**Effects on fertility**
- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Result: negative
- Remarks: Based on data from similar materials

**Effects on fetal development**
- Test Type: Embryo-fetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

### 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**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>
**Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:**

- **Species:** Mouse
- **NOAEL:** 400 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

**Aluminum tristearate:**

- **Species:** Rat
- **NOAEL:** >= 5.000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **Remarks:** Based on data from similar materials

**Benzyl alcohol:**

- **Species:** Rat
- **NOAEL:** 1,072 mg/l
- **Application Route:** Inhalation (dust/mist/fume)
- **Exposure time:** 28 Days
- **Method:** OECD Test Guideline 412

**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

M-Factor (Acute aquatic toxicity): 100
M-Factor (Chronic aquatic toxicity): 1

Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 960 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1.610 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:

NOEC (Pseudokirchneriella subcapitata (green algae)): 17 mg/l
Exposure time: 72 h

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 170 mg/l
Exposure time: 72 h

Toxicity to microorganisms: NOEC (activated sludge): 1.000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Aluminum tristearate:
Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

Benzy alcohol:

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Persistence and degradability

Components:

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

Potassium \[2R-(2\alpha,3Z,5\alpha)-3-(2\text{-hydroxyethylidene})-7\text{-oxo}-4\text{-oxa}-1\text{-azabicyclo}[3.2.0]heptane-2\text{-carboxylate}]:
Biodegradability: Result: Inherently biodegradable.
Biodegradation: 72 %
Exposure time: 28 d

Benzyl alcohol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential

Components:

Amoxicillin Trihydrate:
Partition coefficient: n-octanol/water: log Pow: -0,124
Method: OECD Test Guideline 107

Potassium \[2R-(2\alpha,3Z,5\alpha)-3-(2\text{-hydroxyethylidene})-7\text{-oxo}-4\text{-oxa}-1\text{-azabicyclo}[3.2.0]heptane-2\text{-carboxylate}]:
Partition coefficient: n-octanol/water: log Pow: -5,8
Remarks: Calculation

Benzyl alcohol:
Partition coefficient: n-octanol/water: log Pow: 1,05
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
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.

Domestic regulation

ANTT
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Amoxicillin Trihydrate)
Class: 9
Packing group: III
Labels: 9
Hazard Identification Number: 90

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
National List of Carcinogenic Agents for Humans - (LINACH)
Group 1: Carcinogenic to humans
Silicon, amorphous 112945-52-5
Brazil. List of chemicals controlled by the Federal Police: 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

Further information
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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