SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Supplier’s company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Respiratory sensitisation : Category 1
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 2

GHS label elements

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: P261 Avoid breathing mist or vapours.
P273 Avoid release to the environment.
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.
P391 Collect spillage.

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

**Additional Labelling**
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.

### 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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Trihydrate</td>
<td>61336-70-7</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-625</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td>3-1011</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>1-548</td>
</tr>
</tbody>
</table>

### 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, reac-
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.

5. FIREFIGHTING 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 firefighters

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

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
7. HANDLING AND STORAGE

Handling

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.

Avoidance of contact: Oxidizing agents

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.

Storage

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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / 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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Res-</td>
<td>3 mg/m³</td>
<td>ACGIH</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 vapour type

Hand protection

Material: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: suspension

Colour: cream

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): Not applicable
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.
SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version: 2.2
Revision Date: 2021/08/27
SDS Number: 8845228-00002
Date of last issue: 2021/07/13
Date of first issue: 2021/07/13

Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

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:
  Method: Calculation method
  Acute toxicity estimate: > 2,000 mg/kg
- Acute inhalation toxicity:
  Method: Calculation method
  Acute toxicity estimate: > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist

Components:

Amoxicillin Trihydrate:
- Acute oral toxicity:
  LD50 (Rat): > 8,000 mg/kg
  LD50 (Mouse): > 10,000 mg/kg
  LD50 (Dog): > 3,000 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
Silicon, amorphous:

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 401</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Acute inhalation toxicity:

<table>
<thead>
<tr>
<th>LC50 (Rat): &gt; 2.08 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Acute dermal toxicity:

<table>
<thead>
<tr>
<th>LD50 (Rabbit): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation

Not classified based on available information.

Components:

Aluminum tristearate:

<table>
<thead>
<tr>
<th>Species</th>
<th>reconstructed human epidermis (RhE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 439</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Result: No skin irritation

Benzyl alcohol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

Silicon, amorphous:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Aluminum tristearate:

<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>
SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.2  Revision Date: 2021/08/27  SDS Number: 8845228-00002  Date of last issue: 2021/07/13

Date of first issue: 2021/07/13

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

Silicon, amorphous:
- **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

Aluminum tristearate:
- **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

Benzyl alcohol:
- **Test Type**: Maximisation Test
- **Exposure routes**: 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

Aluminum tristearate:

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

Genotoxicity in vivo: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Benzyl alcohol:

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Silicon, amorphous:

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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>

## Silicon, amorphous:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</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>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Reproductive toxicity**

Not classified based on available information.

# Components:

## Amoxicillin Trihydrate:

### Effects on fertility

<table>
<thead>
<tr>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Fertility: NOAEL: 200 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Reduced fertility</td>
</tr>
<tr>
<td>Remarks: Not classified due to inconclusive data.</td>
</tr>
</tbody>
</table>

### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: &gt;= 1,000 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No embryo-foetal toxicity</td>
</tr>
<tr>
<td>Remarks: Not classified due to inconclusive data.</td>
</tr>
</tbody>
</table>
Developmental Toxicity: LOAEL: 200 mg/kg body weight
Result: Reduced embryonic survival, Reduced offspring weight gain
Remarks: Not classified due to inconclusive data.

**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 foetal 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 foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

**Silicon, amorphous:**

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
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

**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

**Silicon, amorphous:**
- **Species:** Rat
- **NOAEL:** 1.3 mg/l
- **Application Route:** inhalation (dust/mist/fume)
- **Exposure time:** 13 Weeks
- **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.
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

**Amoxicillin Trihydrate:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Carassius auratus (goldfish)): 0.035 mg/l Exposure time: 96 h Method: OECD Test Guideline 203</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>NOEC (green algae): 530 mg/l Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0022 mg/l Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>NOEC (blue-green algae): 0.0057 mg/l Exposure time: 72 h</td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>100</td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>1</td>
</tr>
</tbody>
</table>

**Aluminum tristearate:**

Ecotoxicology Assessment

<table>
<thead>
<tr>
<th>Acute aquatic toxicity</th>
<th>Toxic effects cannot be excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic aquatic toxicity</td>
<td>Toxic effects cannot be excluded</td>
</tr>
</tbody>
</table>

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>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</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic)</td>
<td>NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d</td>
</tr>
</tbody>
</table>
**Silicon, amorphous:**

Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
- Exposure time: 96 h
- Method: OECD Test Guideline 203
- Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
- Exposure time: 24 h
- Method: OECD Test Guideline 202
- Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

Persistence and degradability

**Components:**

**Amoxicillin Trihydrate:**

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

**Benzyl alcohol:**

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

Bioaccumulative potential

**Components:**

**Amoxicillin Trihydrate:**

Bioaccumulation: Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water: log Pow: -0.124
- Method: OECD Test Guideline 107

**Benzyl alcohol:**
11. PARTITION COEFFICIENT: n-octanol/water

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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).

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.

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

IMDG-Code
SAFETY DATA SHEET
Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.2
Revision Date: 2021/08/27
SDS Number: 8845228-00002
Date last issued: 2021/07/13
Date of first issue: 2021/07/13

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
Refer to section 15 for specific national regulation.

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.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

<table>
<thead>
<tr>
<th>Substances Subject to be Notified Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 57-2 (Enforcement Order Table 9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
</table>

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SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.2  Revision Date: 2021/08/27  SDS Number: 8845228-00002  Date of last issue: 2021/07/13

<table>
<thead>
<tr>
<th>Substance</th>
<th>Number</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>530 2</td>
<td>&gt;=1 - &lt;10</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165 2</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

**Substances Subject to be Indicated Names**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>benzyl alcohol</td>
<td>530 2</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165 2</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation: Noxious liquid substance (Category Z)
Pack transportation: Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable
19.2 SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Waste Disposal and Public Cleansing Law

Industrial waste

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

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

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet:

Date format:
- yyyy/mm/dd

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)

- ACGIH / TWA: 8-hour, time-weighted average
- JP OEL JSOH / OEL-C: Occupational Exposure Limit-Ceiling

All - 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 x% growth rate response; ERG - Emergency Response Guide; 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; ICSO - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic Substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temp-
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.