Amoxicillin sodium / Potassium Clavulanate
Mixed in ratio 5:1

Safety Data Sheet
according to Regulation (EU) 2015/830

Date of issue: 03/08/2011        Revision date 06/07/2018
Supersedes 02/07/2014
Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
Product form : Mixture
Trade name : Amoxicillin sodium / Potassium Clavulanate
Mixed in ratio 5:1
Product code : A0189
Formula : C16H19N3O5S (Amoxicillin sodium) / C8H8NO5K (Potassium clavulanate)
Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against
1.2.1. Relevant identified uses
Main use category : Professional use
Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

1.2.2. Uses advised against
No additional information available

1.3. Details of the supplier of the safety data sheet
Supplier
Duchefa Biochemie B.V.
A. Hofmanweg 71
2031 BH Haarlem - The Netherlands
T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.nl

1.4. Emergency telephone number
Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

<table>
<thead>
<tr>
<th>Organisation/Company</th>
<th>Address</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Health Organization world directory of poison centres</td>
<td><a href="http://apps.who.int/poisoncentres/">http://apps.who.int/poisoncentres/</a></td>
<td>Consult website for a local poison centre</td>
</tr>
</tbody>
</table>

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP]
Respiratory sensitisation, Category 1 : H334
Skin sensitisation, Category 1 : H317
Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects
No additional information available
Amoxicillin sodium / Potassium Clavulanate
Mixed in ratio 5:1
Safety Data Sheet
according to Regulation (EU) 2015/830

2.2. Label elements
Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP):

GHS08

Signal word (CLP):
Danger

Hazard statements (CLP):
H317 - May cause an allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements (CLP):
P261 - Avoid breathing dust, fume, gas, mist, spray, vapours.
P280 - Wear Protective clothing, protective gloves, face shield, eye protection.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER/doctor
P302+P352 - IF ON SKIN: Wash with plenty of water.

2.3. Other hazards
No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances
Not applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
</table>
| Amoxicillin trihydrate| (CAS-No.) 61336-70-7     | 83,3| Resp. Sens. 1, H334
|                       | (EC-No.) 248-003-8       |     | Skin Sens. 1, H317                                          |
| Potassium clavulanate | (CAS-No.) 61177-45-5     | 16,7| Flam. Sol. 1, H228                                          |
|                       | (EC-No.) 262-640-9       |     |                                                               |

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general: Seek medical attention if ill effect or irritation develops.
First-aid measures after inhalation: Assure fresh air breathing
If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact: Wash skin with plenty of water and soap
Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact: Rinse with water.
First-aid measures after ingestion: Rinse mouth.
4.2. Most important symptoms and effects, both acute and delayed
Symptoms/effects: Exposure may produce an allergic reaction.
Symptoms/effects after inhalation: Difficulty in breathing.

4.3. Indication of any immediate medical attention and special treatment needed
No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media
Suitable extinguishing media: Alcohol resistant foam.
Dry chemical powder.
Carbon dioxide (CO2).
Water spray.

5.2. Special hazards arising from the substance or mixture
Hazardous decomposition products in case of fire: When heated to decomposition, emits toxic fumes:
- COx
- NOx
- SOx.

5.3. Advice for firefighters
Firefighting instructions: Avoid (reject) fire-fighting water to enter environment.
Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel
Protective equipment: Wear suitable protective clothing.
Measures in case of dust release: Use good housekeeping practices to avoid rendering dust airborne.

6.1.2. For emergency responders
No additional information available

6.2. Environmental precautions
Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up
Methods for cleaning up: Sweep up dry powder and dispose properly. Dispose in a safe manner in accordance with local/national regulations.

6.4. Reference to other sections
No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Precautions for safe handling: Handle in accordance with good industrial hygiene and safety procedures.
7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container tightly closed and dry. Store in dry, cool, well-ventilated area.

Storage temperature: 2 - 8 °C

7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

<table>
<thead>
<tr>
<th>Type</th>
<th>Material</th>
<th>Permeation</th>
<th>Thickness (mm)</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves</td>
<td>Nitrile rubber (NBR)</td>
<td>6 (&gt; 480 minutes)</td>
<td>0,11</td>
<td>EN 374</td>
</tr>
</tbody>
</table>

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear approved mask. Filter type P2 (EN 143)

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Solid
Appearance: Powder.
Colour: White.

Odour: No data available
Odour threshold: No data available
pH: No data available
Relative evaporation rate (butylacetate=1): No data available

Melting point: 252,6 °C
Freezing point: No data available
Boiling point: No data available
Flash point: No data available
Auto-ignition temperature: No data available
 Decomposition temperature: No data available
 Flammability (solid, gas): No data available
 Vapour pressure: No data available
 Relative vapour density at 20 ºC: No data available
 Relative density: No data available
Amoxicillin sodium / Potassium Clavulanate
Mixed in ratio 5:1
Safety Data Sheet
according to Regulation (EU) 2015/830

Solubility : Water: 222 g/l
Log Pow : < 3
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information
Bulk density : 1200 kg/m³

SECTION 10: Stability and reactivity

10.1. Reactivity
Stable under normal conditions of storage, handling and use.

10.2. Chemical stability
Stable under normal conditions.

10.3. Possibility of hazardous reactions
No additional information available

10.4. Conditions to avoid
Moisture.

10.5. Incompatible materials
No additional information available

10.6. Hazardous decomposition products
May liberate toxic gases:
- COx
- NOx
- SOx.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute toxicity : Not classified
Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified
SECTION 12: Ecological information

12.1. Toxicity

<table>
<thead>
<tr>
<th>Amoxicillin sodium / Potassium Clavulanate Mixed in ratio 5:1</th>
<th>EC50 Daphnia 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 1000 mg/l</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>Amoxicillin sodium / Potassium Clavulanate Mixed in ratio 5:1</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 3</td>
</tr>
</tbody>
</table>

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information: Avoid release to the environment. Prevent entry to sewers and public waters

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods: Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

<table>
<thead>
<tr>
<th>ADR</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1. UN number</td>
<td>Not regulated</td>
<td>Not regulated</td>
</tr>
<tr>
<td>14.2. UN proper shipping name</td>
<td>Not regulated</td>
<td>Not regulated</td>
</tr>
<tr>
<td>14.3. Transport hazard class(es)</td>
<td>Not regulated</td>
<td>Not regulated</td>
</tr>
<tr>
<td>14.4. Packing group</td>
<td>Not regulated</td>
<td>Not regulated</td>
</tr>
<tr>
<td>14.5. Environmental hazards</td>
<td>Not regulated</td>
<td>Not regulated</td>
</tr>
</tbody>
</table>

No supplementary information available
14.6. Special precautions for user

- Overland transport
  Not regulated

- Transport by sea
  Not regulated

- Air transport
  Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
  Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

Ensure all national/local regulations are observed.

Germany
Reference to AwSV

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

: Water hazard class (WGK) 3, severe hazard to waters (Classification according to AwSV, Annex 1)

Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen
SZW-lijst van mutagene stoffen
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

: None of the components are listed

Denmark

Recommendations Danish Regulation

: Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

<table>
<thead>
<tr>
<th>1.4</th>
<th>Emergency number</th>
<th>Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Modified</td>
<td></td>
</tr>
</tbody>
</table>
Amoxicillin sodium / Potassium Clavulanate
Mixed in ratio 5:1
Safety Data Sheet
according to Regulation (EU) 2015/830

<table>
<thead>
<tr>
<th>8.2</th>
<th>Hand protection</th>
<th>Modified</th>
<th>Specified material, thickness, etcetera of gloves</th>
</tr>
</thead>
</table>

Abbreviations and acronyms:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATE</td>
<td>Acute Toxicity Estimate</td>
</tr>
<tr>
<td>ADR</td>
<td>European Agreement concerning the International Carriage of Dangerous Goods by Road</td>
</tr>
<tr>
<td>BCF</td>
<td>Bioconcentration factor</td>
</tr>
<tr>
<td>CLP</td>
<td>Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008</td>
</tr>
<tr>
<td>DPD</td>
<td>Dangerous Preparations Directive 1999/45/EC</td>
</tr>
<tr>
<td>DSD</td>
<td>Dangerous Substances Directive 67/548/EEC</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>IMDG</td>
<td>International Maritime Dangerous Goods</td>
</tr>
<tr>
<td>LC50</td>
<td>Median lethal concentration</td>
</tr>
<tr>
<td>LD50</td>
<td>Median lethal dose</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Lowest Observed Adverse Effect Level</td>
</tr>
<tr>
<td>NOAEC</td>
<td>No-Observed Adverse Effect Concentration</td>
</tr>
<tr>
<td>PBT</td>
<td>Persistent Bioaccumulative Toxic</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety Data Sheet</td>
</tr>
</tbody>
</table>

Data sources: Manufacturer. ECHA (European Chemicals Agency).

Full text of H- and EUH-statements:

<table>
<thead>
<tr>
<th>H- or EUH-</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flam. Sol. 1</td>
<td>Flammable solids, Category 1</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>Respiratory sensitisation, Category 1</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Skin sensitisation, Category 1</td>
</tr>
<tr>
<td>H228</td>
<td>Flammable solid.</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>H334</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
</tr>
</tbody>
</table>

SDS Biochemicals version 2018

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.