

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Amoxicillin Trihydrate / Potassium Clavulanate Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 28.09.2024  |
| 4.0     | 14.04.2025     | 9018758-00013 | Date of first issue: 13.07.2021 |

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

#### 1.1 Product identifier

Trade name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|                                                |                                                                                  |
|------------------------------------------------|----------------------------------------------------------------------------------|
| Respiratory sensitisation, Category 1          | H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Skin sensitisation, Category 1                 | H317: May cause an allergic skin reaction.                                       |
| Short-term (acute) aquatic hazard, Category 1  | H400: Very toxic to aquatic life.                                                |
| Long-term (chronic) aquatic hazard, Category 2 | H411: Toxic to aquatic life with long lasting effects.                           |

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

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|                          |   |                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | : |                                                                                                                                                                                                                                                                                                                                                                                                          |
| Signal word              | : | Danger                                                                                                                                                                                                                                                                                                                                                                                                   |
| Hazard statements        | : | H317 May cause an allergic skin reaction.<br>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>H410 Very toxic to aquatic life with long lasting effects.                                                                                                                                                                                                               |
| Precautionary statements | : | <b>Prevention:</b><br>P273 Avoid release to the environment.<br>P280 Wear protective gloves.<br><b>Response:</b><br>P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.<br>P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.<br>P391 Collect spillage. |

### Hazardous components which must be listed on the label:

Amoxicillin Trihydrate  
Benzyl alcohol

### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2.4689 %

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

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| Chemical name          | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                                                                                                                  | Concentration<br>(% w/w) |
|------------------------|-------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Amoxicillin Trihydrate | 61336-70-7                                            | Resp. Sens. 1A;<br>H334<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><br>M-Factor (Acute<br>aquatic toxicity): 100<br>M-Factor (Chronic<br>aquatic toxicity): 1 | >= 10 - < 20             |
| Benzyl alcohol         | 100-51-6<br>202-859-9<br>603-057-00-5                 | Acute Tox. 4; H302<br>Eye Irrit. 2; H319<br>Skin Sens. 1B; H317<br><br>Acute toxicity estimate<br><br>Acute oral toxicity:<br>1,200 mg/kg                                       | >= 1 - < 10              |

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- 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 : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

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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.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).  
  
May cause an allergic skin reaction.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides  
Nitrogen oxides (NO<sub>x</sub>)

### 5.3 Advice for firefighters

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

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

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so.  
Evacuate area.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  
Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.  
Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety

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practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Keep tightly closed.  
Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

| Components                | CAS-No.    | Value type (Form of exposure) | Control parameters | Basis    |
|---------------------------|------------|-------------------------------|--------------------|----------|
| Amoxicillin Trihydrate    | 61336-70-7 | TWA                           | 1 mg/m3 (OEB 1)    | Internal |
| Further information: RSEN |            |                               |                    |          |
| Aluminum tri-stearate     | 637-12-7   | OELV - 8 hrs (TWA)            | 10 mg/m3           | IE OEL   |

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|---------|-----------------|--------------------------|-------|
|----------------|---------|-----------------|--------------------------|-------|

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|                                         |           |              |                            |                    |
|-----------------------------------------|-----------|--------------|----------------------------|--------------------|
| Benzyl alcohol                          | Workers   | Inhalation   | Long-term systemic effects | 22 mg/m3           |
|                                         | Workers   | Inhalation   | Acute systemic effects     | 110 mg/m3          |
|                                         | Workers   | Skin contact | Long-term systemic effects | 8 mg/kg bw/day     |
|                                         | Workers   | Skin contact | Acute systemic effects     | 40 mg/kg bw/day    |
|                                         | Consumers | Inhalation   | Long-term systemic effects | 5.4 mg/m3          |
|                                         | Consumers | Inhalation   | Acute systemic effects     | 27 mg/m3           |
|                                         | Consumers | Skin contact | Long-term systemic effects | 4 mg/kg bw/day     |
|                                         | Consumers | Skin contact | Acute systemic effects     | 20 mg/kg bw/day    |
|                                         | Consumers | Ingestion    | Long-term systemic effects | 4 mg/kg bw/day     |
|                                         | Consumers | Ingestion    | Acute systemic effects     | 20 mg/kg bw/day    |
| Glycerides, mixed decanoyl and octanoyl | Workers   | Inhalation   | Long-term systemic effects | 177.79 mg/m3       |
|                                         | Workers   | Skin contact | Long-term systemic effects | 25.21 mg/kg bw/day |
|                                         | Consumers | Inhalation   | Long-term systemic effects | 43.84 mg/m3        |
|                                         | Consumers | Skin contact | Long-term systemic effects | 12.61 mg/kg bw/day |
|                                         | Consumers | Ingestion    | Long-term systemic effects | 12.61 mg/kg bw/day |

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name                          | Environmental Compartment  | Value           |
|-----------------------------------------|----------------------------|-----------------|
| Benzyl alcohol                          | Fresh water                | 1 mg/l          |
|                                         | Marine water               | 0.1 mg/l        |
|                                         | Intermittent use/release   | 2.3 mg/l        |
|                                         | Sewage treatment plant     | 39 mg/l         |
|                                         | Fresh water sediment       | 5.27 mg/kg      |
|                                         | Marine sediment            | 0.527 mg/kg     |
|                                         | Soil                       | 0.456 mg/kg     |
| Glycerides, mixed decanoyl and octanoyl | Oral (Secondary Poisoning) | 0.03 mg/kg food |

## 8.2 Exposure controls

### Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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Laboratory operations do not require special containment.

### Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection  
Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Filter should conform to I.S. EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic 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 |
| Initial boiling point and boiling range          | : 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 |
| Flash point                                      | : No data available |
| Auto-ignition temperature                        | : No data available |



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|                                        |   |                                 |
|----------------------------------------|---|---------------------------------|
| Decomposition temperature              | : | No data available               |
| pH                                     | : | No data available               |
| Viscosity                              |   |                                 |
| Viscosity, kinematic                   | : | No data available               |
| Solubility(ies)                        |   |                                 |
| Water solubility                       | : | No data available               |
| Partition coefficient: n-octanol/water | : | No data available               |
| Vapour pressure                        | : | Not applicable                  |
| Relative density                       | : | No data available               |
| Density                                | : | 0.900 - 1.100 g/cm <sup>3</sup> |
| Relative vapour density                | : | No data available               |
| Particle characteristics               |   |                                 |
| Particle size                          | : | No data available               |

### 9.2 Other information

|                      |   |                                                          |
|----------------------|---|----------------------------------------------------------|
| Explosives           | : | Not explosive                                            |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate     | : | No data available                                        |
| Molecular weight     | : | No data available                                        |

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

|                     |   |                                         |
|---------------------|---|-----------------------------------------|
| Hazardous reactions | : | Can react with strong oxidizing agents. |
|---------------------|---|-----------------------------------------|

### 10.4 Conditions to avoid

|                     |   |             |
|---------------------|---|-------------|
| Conditions to avoid | : | None known. |
|---------------------|---|-------------|

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### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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: > 2,000 mg/kg  
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

##### Benzyl alcohol:

|| Acute oral toxicity : LD50 (Rat): 1,200 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

#### Skin corrosion/irritation

|| Not classified based on available information.

#### Components:

##### Benzyl alcohol:

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

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### Serious eye damage/eye irritation

|| Not classified based on available information.

#### Components:

##### Benzyl alcohol:

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

### Respiratory or skin sensitisation

#### Skin sensitisation

|| May cause an allergic skin reaction.

#### Respiratory sensitisation

|| May cause allergy or asthma symptoms or breathing difficulties if inhaled.

#### Components:

##### Amoxicillin Trihydrate:

|         |                                                                             |
|---------|-----------------------------------------------------------------------------|
| Result  | : Sensitiser                                                                |
| Remarks | : May cause sensitisation by inhalation.<br>largely based on human evidence |

##### Benzyl alcohol:

|                 |                                          |
|-----------------|------------------------------------------|
| Test Type       | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : Skin contact                           |
| Species         | : Humans                                 |
| Result          | : positive                               |

|            |                                                                                   |
|------------|-----------------------------------------------------------------------------------|
| Assessment | : Probability or evidence of low to moderate skin sensitisation<br>rate in humans |
|------------|-----------------------------------------------------------------------------------|

### Germ cell mutagenicity

|| Not classified based on available information.

#### Components:

##### Amoxicillin Trihydrate:

|                       |                                                                                  |
|-----------------------|----------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative         |
| Genotoxicity in vivo  | : Test Type: Micronucleus test<br>Species: Mouse<br>Result: negative             |
|                       | : Test Type: Rodent dominant lethal test (germ cell) (in vivo)<br>Species: Mouse |

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|| Result: negative

### Benzyl alcohol:

|                       |                                                                                                                                                                        |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                                                                               |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

### Carcinogenicity

|| Not classified based on available information.

### Components:

#### Benzyl alcohol:

|                   |                           |
|-------------------|---------------------------|
| Species           | : Mouse                   |
| Application Route | : Ingestion               |
| Exposure time     | : 103 weeks               |
| Method            | : OECD Test Guideline 451 |
| Result            | : negative                |

### Reproductive toxicity

|| Not classified based on available information.

### Components:

#### Amoxicillin Trihydrate:

|                               |                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility          | : Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 200 mg/kg body weight<br>Result: Reduced fertility<br>Remarks: Not classified due to inconclusive data.<br><br>Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: LOAEL: 500 mg/kg body weight<br>Result: Reduced fertility<br>Remarks: Not classified due to inconclusive data. |
| Effects on foetal development | : Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: $\geq$ 1,000 mg/kg body weight<br>Result: No embryo-foetal toxicity                                                                                                                                                                                                                          |

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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.

### 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

### 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

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|               |                                                |
|---------------|------------------------------------------------|
| Exposure time | : 6 Months                                     |
| Remarks       | : No significant adverse effects were reported |

### 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.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not classified based on available information.

### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### Experience with human exposure

### Components:

#### Amoxicillin Trihydrate:

|           |                                                                                                                                                      |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ingestion | : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, flatulence, skin rash, Breathing difficulties<br>Remarks: May produce an allergic reaction. |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------|

## SECTION 12: Ecological information

### 12.1 Toxicity

### Components:

#### Amoxicillin Trihydrate:

|                                  |                                                                                                                                |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                 | : LC50 (Carassius auratus (goldfish)): 0.035 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203                    |
| Toxicity to algae/aquatic plants | : NOEC (green algae): 530 mg/l<br>Exposure time: 72 h<br><br>EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0022 mg/l |

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|                                                                        |                                                                  |
|------------------------------------------------------------------------|------------------------------------------------------------------|
|                                                                        | 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                                                              |
| <b>Benzyl alcohol:</b>                                                 |                                                                  |
| 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                                  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 51 mg/l                                                  |
|                                                                        | Exposure time: 21 d                                              |
|                                                                        | Species: Daphnia magna (Water flea)                              |
|                                                                        | Method: OECD Test Guideline 211                                  |

### 12.2 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              |

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### 12.3 Bioaccumulative potential

#### Components:

##### **Amoxicillin Trihydrate:**

|                                        |   |                                                    |
|----------------------------------------|---|----------------------------------------------------|
| Bioaccumulation                        | : | Remarks: Bioaccumulation is unlikely.              |
| Partition coefficient: n-octanol/water | : | log Pow: -0.124<br>Method: OECD Test Guideline 107 |

##### **Benzyl alcohol:**

|                                        |   |               |
|----------------------------------------|---|---------------|
| Partition coefficient: n-octanol/water | : | log Pow: 1.05 |
|----------------------------------------|---|---------------|

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

|            |   |                                                                                                                                                                                                    |
|------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment | : | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. |
|------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### Components:

##### **Amoxicillin Trihydrate:**

|            |   |                                                                                                                                                                                            |
|------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment | : | Substance is not persistent, bioaccumulative, and toxic (PBT).. Product does not contain substances which are very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. |
|------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 12.6 Endocrine disrupting properties

#### Product:

|            |   |                                                                                                                                                                                                                                                             |
|------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assessment | : | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |
|------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|         |   |                                                  |
|---------|---|--------------------------------------------------|
| Product | : | Dispose of in accordance with local regulations. |
|---------|---|--------------------------------------------------|



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According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
Do not dispose of waste into sewer.  
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

#### 14.1 UN number or ID number

|      |   |         |
|------|---|---------|
| ADN  | : | UN 3082 |
| ADR  | : | UN 3082 |
| RID  | : | UN 3082 |
| IMDG | : | UN 3082 |
| IATA | : | UN 3082 |

#### 14.2 UN proper shipping name

|      |   |                                                                                 |
|------|---|---------------------------------------------------------------------------------|
| ADN  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Amoxicillin Trihydrate) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Amoxicillin Trihydrate) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Amoxicillin Trihydrate) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Amoxicillin Trihydrate) |
| IATA | : | Environmentally hazardous substance, liquid, n.o.s.<br>(Amoxicillin Trihydrate) |

#### 14.3 Transport hazard class(es)

|      | Class | Subsidiary risks |
|------|-------|------------------|
| ADN  | :     | 9                |
| ADR  | :     | 9                |
| RID  | :     | 9                |
| IMDG | :     | 9                |
| IATA | :     | 9                |

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### 14.4 Packing group

#### ADN

|                              |       |
|------------------------------|-------|
| Packing group                | : III |
| Classification Code          | : M6  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |

#### ADR

|                              |       |
|------------------------------|-------|
| Packing group                | : III |
| Classification Code          | : M6  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |
| Tunnel restriction code      | : (-) |

#### RID

|                              |       |
|------------------------------|-------|
| Packing group                | : III |
| Classification Code          | : M6  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |

#### IMDG

|               |            |
|---------------|------------|
| Packing group | : III      |
| Labels        | : 9        |
| EmS Code      | : F-A, S-F |

#### IATA (Cargo)

|                                      |                 |
|--------------------------------------|-----------------|
| Packing instruction (cargo aircraft) | : 964           |
| Packing instruction (LQ)             | : Y964          |
| Packing group                        | : III           |
| Labels                               | : Miscellaneous |

#### IATA (Passenger)

|                                          |                 |
|------------------------------------------|-----------------|
| Packing instruction (passenger aircraft) | : 964           |
| Packing instruction (LQ)                 | : Y964          |
| Packing group                            | : III           |
| Labels                                   | : Miscellaneous |

### 14.5 Environmental hazards

#### ADN

|                           |       |
|---------------------------|-------|
| Environmentally hazardous | : yes |
|---------------------------|-------|

#### ADR

|                           |       |
|---------------------------|-------|
| Environmentally hazardous | : yes |
|---------------------------|-------|

#### RID

|                           |       |
|---------------------------|-------|
| Environmentally hazardous | : yes |
|---------------------------|-------|

#### IMDG

|                  |       |
|------------------|-------|
| Marine pollutant | : yes |
|------------------|-------|

#### IATA (Passenger)

|                           |       |
|---------------------------|-------|
| Environmentally hazardous | : yes |
|---------------------------|-------|

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### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

|    |               |                     |                     |
|----|---------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|---------------|---------------------|---------------------|

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### HAZARDS

#### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

|                   |   |                                                                                                                                |
|-------------------|---|--------------------------------------------------------------------------------------------------------------------------------|
| Other information | : | Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines. |
|-------------------|---|--------------------------------------------------------------------------------------------------------------------------------|

#### Full text of H-Statements

|      |   |                                                                            |
|------|---|----------------------------------------------------------------------------|
| H302 | : | Harmful if swallowed.                                                      |
| H317 | : | May cause an allergic skin reaction.                                       |
| H319 | : | Causes serious eye irritation.                                             |
| H334 | : | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H400 | : | Very toxic to aquatic life.                                                |
| H410 | : | Very toxic to aquatic life with long lasting effects.                      |

#### Full text of other abbreviations

|                             |   |                                                                                                                               |
|-----------------------------|---|-------------------------------------------------------------------------------------------------------------------------------|
| Acute Tox.                  | : | Acute toxicity                                                                                                                |
| Aquatic Acute               | : | Short-term (acute) aquatic hazard                                                                                             |
| Aquatic Chronic             | : | Long-term (chronic) aquatic hazard                                                                                            |
| Eye Irrit.                  | : | Eye irritation                                                                                                                |
| Resp. Sens.                 | : | Respiratory sensitisation                                                                                                     |
| Skin Sens.                  | : | Skin sensitisation                                                                                                            |
| IE OEL                      | : | Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2 |
| IE OEL / OELV - 8 hrs (TWA) | : | Occupational exposure limit value (8-hour reference period)                                                                   |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -

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European Chemicals Agency; EC-Number - European Community number; 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; 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; IC50 - 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 Standardization; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

|                   |      |
|-------------------|------|
| Resp. Sens. 1     | H334 |
| Skin Sens. 1      | H317 |
| Aquatic Acute 1   | H400 |
| Aquatic Chronic 2 | H411 |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

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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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