

**Amoxicillin Trihydrate / Potassium Clavulanate Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2024/09/28  |
| 5.0     | 2025/04/14     | 8845226-00013 | Date of first issue: 2021/07/13 |

**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

**2. HAZARDS IDENTIFICATION****GHS Classification**

Respiratory sensitisation : Category 1

Skin 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 : H317 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H400 Very toxic to aquatic life.

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H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**

P261 Avoid breathing mist or vapours.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves.  
P284 Wear respiratory protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
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**

| Chemical name          | CAS-No.    | Concentration (% w/w) |
|------------------------|------------|-----------------------|
| Amoxicillin Trihydrate | 61336-70-7 | >= 10 -< 25           |
| Aluminum tristearate   | 637-12-7   | < 10                  |
| Benzyl alcohol         | 100-51-6   | >= 1 -< 10            |

**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.

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|                                                             |                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If inhaled                                                  | : If inhaled, remove to fresh air.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention.                                                                                                                        |
| In case of skin contact                                     | : In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse.                                                          |
| In case of eye contact                                      | : Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                                                                                           |
| If swallowed                                                | : If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water.                                                                                                                                                        |
| Most important symptoms and effects, both acute and delayed | : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).<br>May cause an allergic skin reaction.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical                                                                                                                                                      |
| Unsuitable extinguishing media        | : None known.                                                                                                                                                                                                                                     |
| Specific hazards during fire-fighting | : Exposure to combustion products may be a hazard to health.                                                                                                                                                                                      |
| Hazardous combustion products         | : Carbon oxides<br>Metal oxides<br>Nitrogen oxides (NO <sub>x</sub> )                                                                                                                                                                             |
| Specific extinguishing methods        | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment          | : In the event of fire, wear self-contained breathing apparatus.                                                                                                                                                                                  |

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for firefighters

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 certain local or national requirements.

**7. HANDLING AND STORAGE**

- 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 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

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environment.

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

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

| Components             | CAS-No.                                                                                                                                         | Value type<br>(Form of exposure)    | Control parameters / Permissible concentration | Basis    |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------------|----------|
| Amoxicillin Trihydrate | 61336-70-7                                                                                                                                      | TWA                                 | 1 mg/m <sup>3</sup> (OEB 1)                    | Internal |
|                        | Further information: RSEN                                                                                                                       |                                     |                                                |          |
| Aluminum tristearate   | 637-12-7                                                                                                                                        | NAB                                 | 10 mg/m <sup>3</sup>                           | ID OEL   |
|                        | Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals |                                     |                                                |          |
|                        |                                                                                                                                                 | NAB (Respirable particulate matter) | 1 mg/m <sup>3</sup> (Aluminium)                | ID OEL   |
|                        | Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals |                                     |                                                |          |
|                        |                                                                                                                                                 | TWA (Inhalable particulate matter)  | 10 mg/m <sup>3</sup>                           | ACGIH    |
|                        |                                                                                                                                                 | TWA (Respirable particulate matter) | 3 mg/m <sup>3</sup>                            | ACGIH    |
|                        |                                                                                                                                                 | TWA (Respirable particulate matter) | 1 mg/m <sup>3</sup> (Aluminium)                | ACGIH    |

**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.  
Laboratory operations do not require special containment.

**Personal protective equipment**

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|                          |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Eye protection           | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.                                                                                                                                                                                                                                                                     |
| Skin and body protection | : | Work uniform or laboratory coat.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Hygiene measures         | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>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. |

**9. PHYSICAL AND CHEMICAL PROPERTIES**

|                                         |   |                   |
|-----------------------------------------|---|-------------------|
| Appearance                              | : | suspension        |
| Colour                                  | : | cream             |
| Odour                                   | : | No data available |
| Odour Threshold                         | : | No data available |
| pH                                      | : | No data available |
| Melting point/freezing point            | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point                             | : | No data available |
| Evaporation rate                        | : | No data available |
| Flammability (solid, gas)               | : | Not applicable    |
| Flammability (liquids)                  | : | No data available |

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|                                                  |   |                                                          |
|--------------------------------------------------|---|----------------------------------------------------------|
| Upper explosion limit / Upper flammability limit | : | No data available                                        |
| Lower explosion limit / Lower flammability limit | : | No data available                                        |
| Vapour pressure                                  | : | Not applicable                                           |
| Relative vapour density                          | : | No data available                                        |
| Relative density                                 | : | No data available                                        |
| Density                                          | : | 0.900 - 1.100 g/cm <sup>3</sup>                          |
| Solubility(ies)<br>Water solubility              | : | No data available                                        |
| Partition coefficient: n-octanol/water           | : | No data available                                        |
| Auto-ignition temperature                        | : | No data available                                        |
| Decomposition temperature                        | : | No data available                                        |
| Viscosity<br>Viscosity, kinematic                | : | No data available                                        |
| Explosive properties                             | : | Not explosive                                            |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                                 | : | No data available                                        |
| Particle characteristics<br>Particle size        | : | No data available                                        |

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**10. STABILITY AND REACTIVITY**

|                                    |   |                                                |
|------------------------------------|---|------------------------------------------------|
| Reactivity                         | : | Not classified as a reactivity hazard.         |
| Chemical stability                 | : | Stable under normal conditions.                |
| Possibility of hazardous reactions | : | Can react with strong oxidizing agents.        |
| Conditions to avoid                | : | None known.                                    |
| Incompatible materials             | : | Oxidizing agents                               |
| Hazardous decomposition products   | : | No hazardous decomposition products are known. |

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**11. TOXICOLOGICAL INFORMATION**

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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

**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): 1,200 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:****Aluminum tristearate:**

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

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Remarks : Based on data from similar materials

Result : No skin irritation

**Benzyl alcohol:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Aluminum tristearate:**

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

**Benzyl alcohol:**

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

**Respiratory or skin 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.  
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

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**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 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<br><br>Test Type: Rodent dominant lethal test (germ cell) (in vivo)<br>Species: Mouse<br>Result: negative |

**Aluminum tristearate:**

|                       |                                                                                                                                                                                                                                                                                                                                   |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative<br>Remarks: Based on data from similar materials<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative<br>Remarks: Based on data from similar materials |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 474<br>Result: negative<br>Remarks: Based on data from similar materials                                                                                          |

**Benzyl alcohol:**

|                       |                                                                          |
|-----------------------|--------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|--------------------------------------------------------------------------|

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
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  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 200 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.

Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 500 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.

Effects on foetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL:  $\geq$  1,000 mg/kg body weight  
Result: No embryo-foetal toxicity

Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Some evidence of adverse effects on development, based on animal experiments.

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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.

**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

**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.

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**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             | : $\geq 5,000$ mg/kg                   |
| Application Route | : Ingestion                            |
| Exposure time     | : 90 Days                              |
| Remarks           | : Based on data from similar materials |

**Benzyl alcohol:**

|                   |                               |
|-------------------|-------------------------------|
| Species           | : Rat                         |
| NOAEL             | : 1.072 mg/l                  |
| Application Route | : inhalation (dust/mist/fume) |
| Exposure time     | : 28 Days                     |
| Method            | : OECD Test Guideline 412     |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Amoxicillin Trihydrate:**

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

**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Amoxicillin Trihydrate:**

|                  |                                                   |
|------------------|---------------------------------------------------|
| Toxicity to fish | : LC50 (Carassius auratus (goldfish)): 0.035 mg/l |
|------------------|---------------------------------------------------|

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|                                     | Exposure time: 96 h                                   |
|                                     | Method: OECD Test Guideline 203                       |
| Toxicity to algae/aquatic plants    | : NOEC (green algae): 530 mg/l                        |
|                                     | Exposure time: 72 h                                   |
|                                     | EC50 (Synechococcus leopoliensis (blue-green algae)): |
|                                     | 0.0022 mg/l                                           |
|                                     | Exposure time: 96 h                                   |
|                                     | NOEC (blue-green algae): 0.0057 mg/l                  |
|                                     | Exposure time: 72 h                                   |
| M-Factor (Acute aquatic toxicity)   | : 100                                                 |
| M-Factor (Chronic aquatic toxicity) | : 1                                                   |

**Aluminum tristearate:****Ecotoxicology Assessment**

|                          |                                    |
|--------------------------|------------------------------------|
| Acute aquatic toxicity   | : Toxic effects cannot be excluded |
| Chronic aquatic toxicity | : Toxic effects cannot be excluded |

**Benzyl alcohol:**

|                                                                        |                                                                  |
|------------------------------------------------------------------------|------------------------------------------------------------------|
| Toxicity to fish                                                       | : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l          |
|                                                                        | Exposure time: 96 h                                              |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 230 mg/l                    |
|                                                                        | Exposure time: 48 h                                              |
|                                                                        | Method: OECD Test Guideline 202                                  |
| Toxicity to algae/aquatic plants                                       | : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l |
|                                                                        | Exposure time: 72 h                                              |
|                                                                        | Method: OECD Test Guideline 201                                  |
|                                                                        | NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l   |
|                                                                        | Exposure time: 72 h                                              |
|                                                                        | Method: OECD Test Guideline 201                                  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 51 mg/l                     |
|                                                                        | Exposure time: 21 d                                              |
|                                                                        | Method: OECD Test Guideline 211                                  |

**Amoxicillin Trihydrate / Potassium Clavulanate Formulation**

|                |                              |                              |                                                                   |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|
| Version<br>5.0 | Revision Date:<br>2025/04/14 | SDS Number:<br>8845226-00013 | Date of last issue: 2024/09/28<br>Date of first issue: 2021/07/13 |
|----------------|------------------------------|------------------------------|-------------------------------------------------------------------|

**Persistence and degradability****Components:****Amoxicillin Trihydrate:**

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

**Benzyl alcohol:**

|                  |   |                                                                                    |
|------------------|---|------------------------------------------------------------------------------------|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 92 - 96 %<br>Exposure time: 14 d |
|------------------|---|------------------------------------------------------------------------------------|

**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 |
|----------------------------------------|---|---------------|

**Mobility in soil**

No data available

**Other adverse effects****Components:****Amoxicillin Trihydrate:**

|                                    |   |                                                                                                                                                                                           |
|------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Results of PBT and vPvB 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. |
|------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

|                        |   |                                                                                                |
|------------------------|---|------------------------------------------------------------------------------------------------|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.        |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal. |

**Amoxicillin Trihydrate / Potassium Clavulanate Formulation**

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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.<br>(Amoxicillin Trihydrate) |
| Class                     | : | 9                                                                               |
| Packing group             | : | III                                                                             |
| Labels                    | : | 9                                                                               |
| Environmentally hazardous | : | yes                                                                             |

**IATA-DGR**

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

**IMDG-Code**

|                      |   |                                                                                 |
|----------------------|---|---------------------------------------------------------------------------------|
| UN number            | : | UN 3082                                                                         |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(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.

**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.

**Amoxicillin Trihydrate / Potassium Clavulanate Formulation**

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**15. REGULATORY INFORMATION**

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

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

**16. OTHER INFORMATION**

Revision Date : 2025/04/14

**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/>

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

**Amoxicillin Trihydrate / Potassium Clavulanate Formulation**

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ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

ID OEL / NAB : Long term exposure limit

AIIC - 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; 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; 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 Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

ID / EN