

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Amoxicillin Trihydrate Solid Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/14/2025  |
| 10.0    | 06/17/2025     | 1161183-00022 | Date of first issue: 12/19/2016 |

### SECTION 1. IDENTIFICATION

Product name : Amoxicillin Trihydrate Solid Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Respiratory sensitization : Category 1

#### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.

#### GHS label elements

|                          |                                                                                                                                                                                                                                                                                                          |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | :                                                                                                                                                                                                                     |
| Signal Word              | : Danger                                                                                                                                                                                                                                                                                                 |
| Hazard Statements        | : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.<br>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.                                                                            |
| Precautionary Statements | : <b>Prevention:</b><br>P261 Avoid breathing dust.<br>P285 In case of inadequate ventilation wear respiratory protection.<br><b>Response:</b><br>P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P342 + P311 If experiencing respiratory symptoms: Call a doc- |

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tor.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

| Chemical name          | CAS No./Unique ID | Concentration (% w/w) | Trade secret |
|------------------------|-------------------|-----------------------|--------------|
| Amoxicillin Trihydrate | 61336-70-7*       | $\geq 65 - \leq 85$   | TSC          |
| Polyethylene glycol    | 25322-68-3*       | $\geq 3 - \leq 7$     | TSC          |

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.
- In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
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.

### SECTION 5. FIRE-FIGHTING MEASURES

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- |                                                |                                                                                                                                                                                                                                                   |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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          | : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                  | : Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Metal oxides                                                                                                                                                                             |
| 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 for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Environmental precautions                                           | : Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Methods and materials for containment and cleaning up               | : Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.<br>Add excess liquid to allow the material to enter into solution.<br>Soak up with inert absorbent material.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.<br>Clean up remaining materials from spill with suitable absorbent.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items |

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employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

- |                             |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical measures          | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Local/Total ventilation     | : | Use only with adequate ventilation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Advice on safe handling     | : | Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

- |                        |                                                                                                           |
|------------------------|-----------------------------------------------------------------------------------------------------------|
| inert or nuisance dust | 50 Million particles per cubic foot<br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3 |
|                        | 15 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3                |
|                        | 5 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (respirable fraction)<br>Basis: OSHA Z-3        |

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15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates      10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

| Components                | CAS-No.    | Value type (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 |            |                               |                                                |          |
| Polyethylene glycol       | 25322-68-3 | TWA (aerosol)                 | 10 mg/m <sup>3</sup>                           | US WEEL  |

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection  
Material : Chemical-resistant gloves

Eye 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.

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.  
When using do not eat, drink or smoke.

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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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Appearance                                       | : | powder                                                                          |
| Color                                            | : | white                                                                           |
| Odor                                             | : | characteristic                                                                  |
| Odor Threshold                                   | : | No data available                                                               |
| pH                                               | : | 5.5 - 7.5<br>(as aqueous solution)                                              |
| Melting point/freezing point                     | : | No data available                                                               |
| Initial boiling point and boiling range          | : | No data available                                                               |
| Flash point                                      | : | Not applicable                                                                  |
| Evaporation rate                                 | : | Not applicable                                                                  |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | No data available                                                               |
| Upper explosion limit / Upper flammability limit | : | No data available                                                               |
| Lower explosion limit / Lower flammability limit | : | No data available                                                               |
| Vapor pressure                                   | : | Not applicable                                                                  |
| Relative vapor density                           | : | Not applicable                                                                  |
| Relative density                                 | : | No data available                                                               |
| Density                                          | : | No data available                                                               |
| Solubility(ies)                                  |   |                                                                                 |
| Water solubility                                 | : | 1.43 g/l                                                                        |
| Partition coefficient: n-octanol/water           | : | Not applicable                                                                  |
| Autoignition temperature                         | : | No data available                                                               |

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|                           |   |                                                          |
|---------------------------|---|----------------------------------------------------------|
| Decomposition temperature | : | No data available                                        |
| Viscosity                 |   |                                                          |
| Viscosity, kinematic      | : | Not applicable                                           |
| Explosive properties      | : | Not explosive                                            |
| Oxidizing properties      | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight          | : | No data available                                        |
| Particle characteristics  |   |                                                          |
| Particle size             | : | No data available                                        |

### SECTION 10. STABILITY AND REACTIVITY

|                                    |   |                                                                                                                            |
|------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------|
| Reactivity                         | : | Not classified as a reactivity hazard.                                                                                     |
| Chemical stability                 | : | Stable under normal conditions.                                                                                            |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.                                                                          |
| Incompatible materials             | : | Oxidizing agents                                                                                                           |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.                                                                             |

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Amoxicillin Trihydrate:

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

##### Polyethylene glycol:

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|                       |                                                                                                                 |
|-----------------------|-----------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity   | : LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 423<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : LD50 (Rat): > 2,000 mg/kg<br>Remarks: Based on data from similar materials                                    |

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Polyethylene glycol:

|         |                                        |
|---------|----------------------------------------|
| Species | : Rabbit                               |
| Method  | : OECD Test Guideline 404              |
| Result  | : No skin irritation                   |
| Remarks | : Based on data from similar materials |

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Polyethylene glycol:

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

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

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

### Components:

#### Amoxicillin Trihydrate:

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

#### Polyethylene glycol:

|                    |                                        |
|--------------------|----------------------------------------|
| Test Type          | : Maximization Test                    |
| Routes of exposure | : Skin contact                         |
| Species            | : Guinea pig                           |
| Result             | : negative                             |
| Remarks            | : Based on data from similar materials |



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### 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 |

#### Polyethylene glycol:

|                       |                                                                                                                           |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br>Remarks: Based on data from similar materials |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------|

### Carcinogenicity

Not classified based on available information.

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Some evidence of adverse effects on development, based on animal experiments.  
Remarks: Not classified due to inconclusive data.

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Reduced embryonic survival, Reduced offspring weight gain.  
Remarks: Not classified due to inconclusive data.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Components:

#### Amoxicillin Trihydrate:

Remarks : Not classified due to inconclusive data.

### Repeated dose toxicity

### Components:

#### Amoxicillin Trihydrate:

Species : Rat  
Application Route : Oral  
Exposure time : 6 Months  
Remarks : No significant adverse effects were reported

Species : Dog  
Application Route : Oral  
Exposure time : 6 Months  
Remarks : No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

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### Experience with human exposure

#### Components:

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

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

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

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

|                                  |                                                                                                                                                                                                                          |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                 | : LC50 (Carassius auratus (goldfish)): 0.035 mg/l<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<br>Exposure time: 96 h<br><br>NOEC (blue-green algae): 0.0057 mg/l<br>Exposure time: 72 h |

##### **Polyethylene glycol:**

|                  |                                                                                                                                                             |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish | : LC50 (Poecilia reticulata (guppy)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: Based on data from similar materials |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Persistence and degradability

#### Components:

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

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

##### **Polyethylene glycol:**

|                  |                                                                               |
|------------------|-------------------------------------------------------------------------------|
| Biodegradability | : Result: rapidly degradable<br>Remarks: Based on data from similar materials |
|------------------|-------------------------------------------------------------------------------|

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### 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 |

##### Polyethylene glycol:

|                                        |   |              |
|----------------------------------------|---|--------------|
| Partition coefficient: n-octanol/water | : | log Pow: < 3 |
|----------------------------------------|---|--------------|

### 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. |
|------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

|                           |   |                                                                                |
|---------------------------|---|--------------------------------------------------------------------------------|
| UN number                 | : | UN 3077                                                                        |
| Proper shipping name      | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(Amoxicillin Trihydrate) |
| Class                     | : | 9                                                                              |
| Packing group             | : | III                                                                            |
| Labels                    | : | 9                                                                              |
| Environmentally hazardous | : | yes                                                                            |

#### IATA-DGR

|                      |   |                                                    |
|----------------------|---|----------------------------------------------------|
| UN/ID No.            | : | UN 3077                                            |
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. |

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(Amoxicillin Trihydrate)

|                                          |   |               |
|------------------------------------------|---|---------------|
| Class                                    | : | 9             |
| Packing group                            | : | III           |
| Labels                                   | : | Miscellaneous |
| Packing instruction (cargo aircraft)     | : | 956           |
| Packing instruction (passenger aircraft) | : | 956           |
| Environmentally hazardous                | : | yes           |

### IMDG-Code

|                      |   |                                                    |
|----------------------|---|----------------------------------------------------|
| UN number            | : | UN 3077                                            |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |

(Amoxicillin Trihydrate)

|                  |   |          |
|------------------|---|----------|
| Class            | : | 9        |
| Packing group    | : | III      |
| Labels           | : | 9        |
| EmS Code         | : | F-A, S-F |
| Marine pollutant | : | yes      |

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

|                      |   |                                                                                                                                                                                                                                                         |
|----------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| UN/ID/NA number      | : | UN 3077                                                                                                                                                                                                                                                 |
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. (Amoxicillin Trihydrate)                                                                                                                                                                             |
| Class                | : | 9                                                                                                                                                                                                                                                       |
| Packing group        | : | III                                                                                                                                                                                                                                                     |
| Labels               | : | CLASS 9                                                                                                                                                                                                                                                 |
| ERG Code             | : | 171                                                                                                                                                                                                                                                     |
| Marine pollutant     | : | yes(Amoxicillin Trihydrate)                                                                                                                                                                                                                             |
| Remarks              | : | Above applies only to containers over 119 gallons or 450 liters.<br>Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO. |

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

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## Amoxicillin Trihydrate Solid Formulation

|         |                |               |                                 |
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### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust  
Respiratory or skin sensitization

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

|                          |            |
|--------------------------|------------|
| Amoxicillin Trihydrate   | 61336-70-7 |
| Sodium glycine carbonate | 50610-34-9 |
| Polyethylene glycol      | 25322-68-3 |

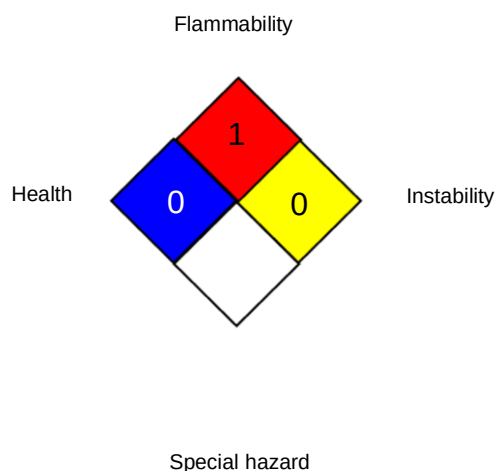
#### The ingredients of this product are reported in the following inventories:

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

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 0 |
| FLAMMABILITY    |   | 3 |
| PHYSICAL HAZARD |   | 0 |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)

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|                |   |                                                                    |
|----------------|---|--------------------------------------------------------------------|
| OSHA Z-3       | : | USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts |
| US WEEL        | : | USA. Workplace Environmental Exposure Levels (WEEL)                |
| CAL PEL / PEL  | : | Permissible exposure limit                                         |
| OSHA Z-3 / TWA | : | 8-hour time weighted average                                       |
| US WEEL / TWA  | : | 8-hr TWA                                                           |

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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

Revision Date : 06/17/2025

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

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

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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.

US / Z8