

SAFETY DATA SHEET

according to the Globally Harmonized System



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 8845227-00013 Date of last issue: 28.09.2024
Date of first issue: 13.07.2021

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Acute toxicity (Inhalation) : Category 4

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

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Hazard statements	: H317 May cause an allergic skin reaction. H332 Harmful if inhaled. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.
Precautionary statements	: Prevention: P233 Keep container tightly closed. P260 Do not breathe mist or vapours. P271 Use only outdoors or with adequate ventilation. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing. P284 Wear respiratory protection. Response: P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 + P317 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help. P333 + P317 If skin irritation or rash occurs: Get medical help. P342 + P316 If experiencing respiratory symptoms: Get emergency medical help immediately. P362 + P364 Take off contaminated clothing and wash it before reuse. P391 Collect spillage. Storage: P403 Store in a well-ventilated place. 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)
Glycerides, mixed decanoyl and octanoyl	73398-61-5	>= 70 - < 90
Amoxicillin Trihydrate	61336-70-7	>= 10 - < 20

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Potassium [2R-(2a,3Z,5a)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate	61177-45-5	>= 1 - < 5
Aluminum tristearate	637-12-7	>= 1 - < 5
Benzyl alcohol	100-51-6	>= 1 - < 5

Alternative CAS Numbers for some regions

Chemical name	Alternative CAS Number(s)
Glycerides, mixed decanoyl and octanoyl	52622-27-2

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

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
May cause an allergic skin reaction.
Harmful if inhaled.
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
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

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Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Metal oxides Nitrogen oxides (NOx)
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding 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.

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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 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 (Form of exposure)	Control parameters / Permissible concentration	Basis
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal
Further information: RSEN				
Aluminum tristearate	637-12-7	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
		TWA (Respirable particulate matter)	1 mg/m3 (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

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

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Filter type	sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Hand protection	: Combined particulates and organic vapour type
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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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
Upper explosion limit / Upper	: No data available

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flammability limit

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/cm³

Solubility(ies)

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

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

Particle size : No data available

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion

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Eye contact

Acute toxicity

Harmful if inhaled.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 1.92 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Glycerides, mixed decanoyl and octanoyl:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 1.86 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Amoxicillin Trihydrate:

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

Potassium [2R-(2 α ,3Z,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Acute oral toxicity : LD50 (Mouse): 4,526 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

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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:

Glycerides, mixed decanoyl and octanoyl:

Species	: Rabbit
Result	: No skin irritation

Potassium [2R-(2 α ,3Z,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

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

Aluminum tristearate:

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

Glycerides, mixed decanoyl and octanoyl:

Species	: Rabbit
Result	: No eye irritation

Potassium [2R-(2 α ,3Z,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

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Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	No eye irritation

Aluminum tristearate:

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

Benzyl alcohol:

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

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

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

Components:

Glycerides, mixed decanoyl and octanoyl:

Test Type	:	Buehler Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

Amoxicillin Trihydrate:

Result	:	Sensitiser
Remarks	:	May cause sensitisation by inhalation. largely based on human evidence

Potassium [2R-(2 α ,3 Z ,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

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

Aluminum tristearate:

Test Type	:	Local lymph node assay (LLNA)
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Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	negative
Remarks	:	Based on data from similar materials

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:

Glycerides, mixed decanoyl and octanoyl:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: Directive 67/548/EEC, Annex, B.13/14 Result: negative Remarks: Based on data from similar materials
		Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
		Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials
		Test Type: In vitro sister chromatid exchange assay in mammalian cells Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Amoxicillin Trihydrate:

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

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	Species: Mouse Result: negative
	Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Result: negative

Potassium [2R-(2 α ,3Z,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

Aluminum tristearate:

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

Benzyl alcohol:

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

Carcinogenicity

Not classified based on available information.

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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:

Glycerides, mixed decanoyl and octanoyl:

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: Embryo-foetal development Species: Rat Application Route: Intravenous injection Result: negative Remarks: Based on data from similar materials

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: >= 1,000 mg/kg body weight Result: No embryo-foetal toxicity
	:	Test Type: Development Species: Mouse Application Route: Oral

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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.

Potassium [2R-(2 α ,3Z,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Intravenous injection
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Intravenous injection
Result: negative

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

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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:

Glycerides, mixed decanoyl and octanoyl:

||| Species : Rat
||| NOAEL : 5,000 mg/kg
||| Application Route : Ingestion
||| Exposure time : 13 Weeks
||| Remarks : Based on data from similar materials

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

Potassium [2R-(2 α ,3 Z ,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

||| Species : Mouse
||| NOAEL : 400 mg/kg
||| Application Route : Ingestion
||| Exposure time : 90 Days

Aluminum tristearate:

||| Species : Rat
||| NOAEL : >= 5,000 mg/kg
||| Application Route : Ingestion
||| Exposure time : 90 Days
||| Remarks : Based on data from similar materials

Benzyl alcohol:

||| Species : Rat
||| NOAEL : 1.072 mg/l

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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:

Glycerides, mixed decanoyl and octanoyl:

Toxicity to fish	:	LL50 (Danio rerio (zebra fish)): > 1,000 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.1.
Toxicity to daphnia and other aquatic invertebrates	:	EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EL10 (Desmodesmus subspicatus (green algae)): > 1,000 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.3.
		EL50 (Desmodesmus subspicatus (green algae)): > 1,000 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.3.
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: >= 0.01 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Test substance: Water Accommodated Fraction Method: OECD Test Guideline 211 Remarks: Based on data from similar materials No toxicity at the limit of solubility

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Amoxicillin Trihydrate:

Toxicity to fish

: LC50 (Carassius auratus (goldfish)): 0.035 mg/l
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

Potassium [2R-(2 α ,3 β ,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Toxicity to fish

: LC50 (Oncorhynchus mykiss (rainbow trout)): > 960 mg/l
Exposure time: 96 h
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 1,610 mg/l
Exposure time: 48 h
Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic plants

: NOEC (Pseudokirchneriella subcapitata (green algae)): 17 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 170 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.

Toxicity to microorganisms

: NOEC (activated sludge): 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Aluminum tristearate:

Ecotoxicology Assessment

Acute aquatic toxicity

: Toxic effects cannot be excluded

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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: 51 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Persistence and degradability

Components:

Glycerides, mixed decanoyl and octanoyl:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 95.4 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Amoxicillin Trihydrate:

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

Potassium [2R-(2 α ,3 β ,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Biodegradability : Result: Inherently biodegradable.
Biodegradation: 72 %
Exposure time: 28 d

Benzyl alcohol:

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

Bioaccumulative potential

Components:

Glycerides, mixed decanoyl and octanoyl:

Partition coefficient: n-octanol/water : log Pow: > 8

Amoxicillin Trihydrate:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

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

Potassium [2R-(2 α ,3 β ,5 α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Partition coefficient: n-octanol/water : log Pow: -5.8
Remarks: Calculation

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.
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Amoxicillin Trihydrate)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

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

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Amoxicillin Trihydrate)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments

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.

15. REGULATORY INFORMATION

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

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

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

16. OTHER INFORMATION

Revision Date : 14.04.2025

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 : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

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 Recom-

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mendations 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.

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