SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.0	06.07.2024	8845213-00011	Date of first issue: 13.07.2021

SECTION 1. IDENTIFICATION

Product name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Respiratory sensitization : 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 : 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:

P261 Avoid breathing mist or vapors.

P273 Avoid release to the environment.
P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P391 Collect spillage.

Disposal:

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

Additional Labeling

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	>= 10 -< 20
Potassium [2R-(2α,3Z,5α)]-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

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 as a precaution.
Get medical attention if symptoms occur.

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

delayed		Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
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

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) 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 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Avoid breathing mist or vapors. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. 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. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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	CMP	10 mg/m³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH
		TWA	1 mg/m³	ACGIH

		(Respirable particulate matter)	(Aluminum)	

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapor type

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.
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	:	suspension
Color	:	cream
Odor	:	No data available
Odor 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 flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor 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
Autoignition 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

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

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: > 5.000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist 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

Potassium [2R-(2α,3Z,5α)]-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

Benzyl alcohol:

Acute oral toxicity	:	LD50 (Rat): 1.620 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 4,178 mg/l Exposure time: 4 h

Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Skin corrosion/irritation

Not classified based on available information.

Components:

Potassium [2R-(2α,3Z,5α)]-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:

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

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

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 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. largely based on human evidence

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

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

Benzyl alcohol:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Amoxicillin Trihydrate:

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

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

Potassium [2R-(2α,3Z,5α)]-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.

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 fetal development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: >= 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.

Potassium [2R-(2α,3Z,5α)]-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 fetal 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 fetal 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 fetal development	:	Test Type: Embryo-fetal development Species: Mouse Application Route: Ingestion Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:

Amoxicillin Trihydrate:

Remarks	:	Not classified due to inconclusive data.

Repeated dose toxicity

Components:

Amoxicillin Trihydrate:

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

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

Potassium [2R-(2α,3Z,5α)]-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
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, Diarrhea, flatulence, skin rash, Breathing difficulties 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 Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae/aquatic	:	NOEC (green algae): 530 mg/l

plants		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-(2α,3Z,5α)]-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
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

Persistence and degradability

Components:

Amoxicillin Trihydrate:

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

Potassium [2R-(2α,3Z,5α)]-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:

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

Bioaccumulative potential

Components:

Amoxicillin Trihydrate:

Bioaccumulation	:	Remarks: Bioaccumulation is unlikely.
Partition coefficient: n-octanol/water	:	log Pow: -0,124 Method: OECD Test Guideline 107

Potassium [2R-(2α,3Z,5α)]-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.

SECTION 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.

SECTION 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 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.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable

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

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

SECTION 16. OTHER INFORMATION

Revision Date	:	06.07.2024
Date format	:	dd.mm.yyyy

Further information

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/

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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
AR OEL / CMP	:	TLV (Threshold Limit Value)

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.

AR / Z8