

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
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 : 91-105 Harpin Street
Bendigo 3550, Victoria Australia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

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 sensitisation : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements :

Prevention:

P261 Avoid breathing mist or vapours.

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.

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
 Date of first issue: 13.07.2021

Disposal:

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

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 - < 30
Aluminum tristearate	637-12-7	< 10
Benzyl alcohol	100-51-6	< 10

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

- Suitable extinguishing media : Water spray
 Alcohol-resistant foam

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.6	01.11.2023	8845220-00009	Date of first issue: 13.07.2021

		Carbon dioxide (CO ₂)
		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 (NO _x)
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.
Hazchem Code	:	•3Z

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 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.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE
--------------------	---	---

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
Date of first issue: 13.07.2021

Local/Total ventilation	:	CONTROLS/PERSONAL PROTECTION section. Use only with adequate ventilation.
Advice on safe handling	:	Avoid breathing mist or vapours. 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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. 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.
Conditions for safe storage	:	Keep in properly labelled 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

SECTION 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/m ³ (OEB 1)	Internal
Further information: RSEN				
Aluminum tristearate	637-12-7	TWA	10 mg/m ³	AU OEL
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
		TWA (Res-	1 mg/m ³	ACGIH

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
 Date of first issue: 13.07.2021

		pirable particulate matter)	(Aluminium)	
--	--	-----------------------------	-------------	--

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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
 Filter type : Combined particulates and organic vapour type
 Hand protection :
 Material : Chemical-resistant gloves
 Eye protection : Wear safety glasses with side shields or goggles.
 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.

SECTION 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

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.6	01.11.2023	8845220-00009	Date of first issue: 13.07.2021

Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	0.900 - 1.100 g/cm ³
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 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.

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
Date of first issue: 13.07.2021

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 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

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.

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
Date of first issue: 13.07.2021

Components:

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:

Aluminum tristearate:

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

Benzyl alcohol:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

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

Components:

Amoxicillin Trihydrate:

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

Aluminum tristearate:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
Date of first issue: 13.07.2021

Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Benzyl alcohol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Chronic toxicity**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

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

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
Date of first issue: 13.07.2021

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

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
 Date of first issue: 13.07.2021

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.

Aluminum tristearate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 416
 Result: negative
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative
 Remarks: Based on data from similar materials

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Mouse
 Application Route: Ingestion
 Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
Date of first issue: 13.07.2021

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

Aluminum tristearate:

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

Benzyl alcohol:

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

Aspiration toxicity

Not classified based on available information.

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

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

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
Date of first issue: 13.07.2021

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 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

Aluminum tristearate:**Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 2.6 Revision Date: 01.11.2023 SDS Number: 8845220-00009 Date of last issue: 30.09.2023
Date of first issue: 13.07.2021

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

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

Benzyl alcohol:

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

Bioaccumulative potential**Components:****Amoxicillin Trihydrate:**

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

Benzyl alcohol:

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

Mobility in soil

No data available

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

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This mixture contains no substance considered to be very persistent and very bioaccumulating (vPvB).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.6	01.11.2023	8845220-00009	Date of first issue: 13.07.2021

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.

National Regulations

ADG

UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
 (Amoxicillin Trihydrate)
 Class : 9

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.6	01.11.2023	8845220-00009	Date of first issue: 13.07.2021

Packing group : III
Labels : 9
Hazchem Code : •3Z
Environmentally hazardous : yes

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**

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

Revision Date : 01.11.2023
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/>
Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.6	01.11.2023	8845220-00009	Date of first issue: 13.07.2021

ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - 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; KECl - 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; TECl - 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.

AU / EN