

1. Product and Company Identification

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Product Name Amoxicillin Trihydrate

Part Number RXSOL-19-1101-026

Company Details:

RX MARINE INTERNATIONAL
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2. Composition / Information on ingredients

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Chemical Name	Cas No	EC No	Weight	Formula
Amoxicillin Trihydrate	61336-70-7	933-899-1	419,45 g/mol	C ₁₆ H ₁₉ N ₃ O ₅ S · 3H ₂ O

3. Hazards Identification

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Signal Word	Danger
Hazard Statements	H300 + H310 Fatal if swallowed or in contact with skin.
Precautionary statements	P262 Do not get in eyes, on skin, or on clothing. P280 Wear protective gloves/ protective clothing. P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth. P302 + P352 + P310 IF ON SKIN: Wash with plenty of water. Immediately call a POISON CENTER/ doctor.
Classification of the substance or mixture	Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.
Supplemental Hazard Statements	None
Other hazards	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

4. First Aid Measures

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General advice	First aiders need to protect themselves. Show this material safety data sheet to the doctor in attendance.
If inhaled	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
Eye Contact	After eye contact: rinse out with plenty of water. Remove contact lenses.
Swallowed	After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.
Skin Contact	In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.
Inhalation	fresh air. Call in physician.
Ingestion	Rinse mouth with water. Do not induce vomiting. Never give anything by

Most important symptoms and effects, both acute and delaye

mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

Indication of any immediate medical attention and special treatment needed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

No data available

5. Fire-fighting Measures

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Flammability

May be combustible at high temperature.

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

Special hazards arising from the substance or mixture

Carbon oxides Nitrogen oxides (NO_x) Sulfur oxides Combustible. Development of hazardous combustion gases or vapours possible in the event of fire.

Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

Hazardous combustion products

Fire may cause the evolution of Sulphur oxides, nitrogen oxides.

Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Protective Equipment

Use personal protective equipment.

Specific Hazards Arising from the Chemical

Has a fire-promoting effect due to the release of oxygen. Ambient fire may liberate hazardous vapours.

6. Accidental Release Measures

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Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.

Spillage

Oxidizing material. Stop leak if without risk. Avoid contact with a combustible material (wood, paper, oil, clothing...). Keep substance damp using water spray. Do not touch spilled material. Prevent entry into sewers, basements or confined areas dike if needed. Eliminate all ignition sources. Call for assistance on disposal.

Personal Protection

Advice for non-emergency personnel: Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert. Advice for emergency responders: Protective equipment see section 8.

Enviromental Precaution

Do not let product enter drains.

Methods and materials for containment and cleaning

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully. Dispose of properly. Clean up affected area. Avoid generation of dusts.

Reference to other sections

For disposal see section 13.

7. Handling and Storage

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Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take measures to prevent the build up of electrostatic charge.

Incompatible materials

Keep away from alkalis, strong oxidizing agents and metals. Provide containment walls of adequate capacity to hold any accidental spills.

Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance. For

Advice on safe handling	precautions see section 2.2.
Conditions for safe storage, including any incompatibilities	Work under hood. Do not inhale substance/mixture.
Storage conditions	Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons. Moisture sensitive.
Storage class	Tightly closed. Dry. Keep locked up or in an area accessible only to qualified or authorized persons.
Specific end use(s)	Storage class (TRGS 510): 11: Combustible Solids
Advice on general occupational hygiene	Apart from the uses mentioned in section 1.2 no other specific uses are stipulated
	Advice on safe handling Observe label precautions. Change contaminated clothing. Wash hands after working with substance.

8. Exposure controls and personal protection

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Exposure controls	No specific additional engineering controls are required. Provide good natural or artificial ventilation.
Engineering Control	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Eye/face protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses
Body Protection	protective clothing
Skin protection	This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de). Full contact Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 480 min Material tested:KCL 741 Dermatril® L Splash contact Material: Nitrile rubber Minimum layer thickness: 0,11 mm Break through time: 480 min Material tested:KCL 741 Dermatril® L
Respiratory protection	Required when dusts are generated. Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system. Recommended Filter type: Filter type P2 The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.
Other Protection Measure	Handle in accordance with good industrial hygiene and safety practice.
Control of environmental exposure	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

9. Physical and chemical properties

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Physical state	solid
Colour	No data available
Odour	No data available
Odor Threshold	Not Applicable
pH	No data available
Melting Point	No data available
Boiling Point	No data available
Flash Point	No data available
Evaporation Rate	Not Applicable
Flammability (solid, gas)	No data available
Explosive limits	No Data Available

Upper/lower flammability or explosive limits	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Vapour pressure	No data available
Viscosity	No data available
Density	No data available
Relative Density	No data available
Specific Gravity	No data available
Partition coefficient	No data available
Explosive properties	No data available
Solubility	No data available
Ignition temperature	No information available.
Particle characteristics	No data available

10. Stability and reactivity

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Reactivity	The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.
Chemical stability	The product is chemically stable under standard ambient conditions (room temperature) .
Possibility of hazardous reactions	No data available
Conditions to avoid	Heat, flames and sparks.
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products	In the event of fire: see section 5

11. Toxicological information

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Acute toxicity	LD50 Oral - Rat - female - > 2.000 mg/kg (OECD Test Guideline 423) Remarks: (anhydrous substance) The value is given in analogy to the following substances: Amoxicillin Inhalation: No data available LD50 Dermal - Rat - male and female - > 2.000 mg/kg (OECD Test Guideline 402) Remarks: (anhydrous substance) The value is given in analogy to the following substances: AmoxicillinThe value is given in analogy to the following substances: Amoxicillin T trihydrate
Skin corrosion/irritation	Skin - In vitro study Result: No skin irritation - 15 min (OECD Test Guideline 439) Remarks: (anhydrous substance) The value is given in analogy to the following substances: AmoxicillinThe value is given in analogy to the following substances: Amoxicillin T trihydrate
Serious eye damage/irritation	Eyes - Rabbit Result: No eye irritation (OECD Test Guideline 405) Remarks: (anhydrous substance) The value is given in analogy to the following substances: AmoxicillinThe value is given in analogy to the following substances: Amoxicillin T trihydrate
Respiratory or skin sensitization	No data available
Carcinogenicity	No data available
Germ cell mutagenicity	Test Type: Chromosome aberration test in vitro Test system: Human lymphocytes Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 473 Result: negative Remarks: (anhydrous substance) The value is given in analogy to the following substances: AmoxicillinThe value is given in analogy to the following substances: Amoxicillin T trihydrateTest Type: Micronucleus test Test system: Human lymphocytes Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 487 Result: negative Remarks: (anhydrous substance) The value is given in analogy to the following substances: AmoxicillinThe value is given in analogy to the following substances: Amoxicillin T trihydrateTest Type: In vitro mammalian cell gene mutation test Test system: Mouse lymphoma test Metabolic

Reproductive toxicity
Specific target organ toxicity - single exposure
Additional Information

activation: with and without metabolic activation Method: OECD Test Guideline 490 Result: negative
May cause allergic respiratory and skin reactions (anhydrous substance)
No data available
RTECS: UF9625000 Lung irritation, Cyanosis, Central nervous system depression To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. Ecological information

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Persistence and degradability

No data available

Toxicity to fish

Static test LC50 - Oncorhynchus mykiss (rainbow trout) - 75 mg/l - 96 h (OECD Test Guideline 203)

Toxicity to daphnia and other aquatic invertebrates

Static test EC50 - Daphnia magna (Water flea) - 42,81 mg/l - 48 h (OECD Test Guideline 202) Remarks: (in analogy to similar products) The value is given in analogy to the following substances: maleic acid

Toxicity

Toxicity to fish LC50 - Pimephales promelas (fathead minnow) - 1.520 mg/l - 96 h

Toxicity to bacteria

EC10 - Bacteria - 14 mg/l - 72 h Remarks: (Lit.) EC5 - E.coli - 15.000 mg/l Remarks: (Lit.) (maximum permissible toxic concentration)

Toxicity to algae

Static test ErC50 - Pseudokirchneriella subcapitata (green algae) - 74,35 mg/l - 72 h (OECD Test Guideline 201) Remarks: (in analogy to similar products) The value is given in analogy to the following substances: maleic acid

Products Biodegradation

The methods for determining the biological degradability are not applicable to inorganic substances.

Mobility in soil

No data available

Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Endocrine disrupting properties

No data available

Other adverse effects

No data available .

13. Disposal considerations

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Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Contaminated packaging

Dispose of as unused product.

Waste treatment Method

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

14. Transport information

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UN number

ADR/RID: IMDG: IATA:

UN proper shipping name

ADR/RID: IMDG: IATA:

Transport hazard class(es)

ADR/RID: IMDG: IATA:

Packaging group

ADR/RID: IMDG: IATA:

Environmental hazards

ADR/RID: No IMDG: No IATA: No

Special precautions for user

No data available

Further information

Not classified as dangerous in the meaning of transport regulations.

15. Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Other regulations

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable. Take note of Dir 94/33/EC on the protection of young people at work.

Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

16. Other information

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Other Information

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall we be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Rx Marine International has been advised of the possibility of such damages.

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