

## 1. Product and Company Identification

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Product Name Atorvastatin calcium Trihydrate  
Part Number RXSOL-19-1605-156

### Company Details:

RX MARINE INTERNATIONAL  
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## 2. Composition / Information on ingredients

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Chemical Name	Cas No	EC No	Whight	Formula
Atorvastatin calcium salt trihydrate	344423-98-9	686-242-3	1.209,38 g/mol	$C_{66}H_{68}CaF_2N_4O_{10} \cdot 3H_2O$

## 3. Hazards Identification

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Signal Word	Danger
Hazard Statements	H351 Suspected of causing cancer. H360D May damage the unborn child.
Precautionary statements	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P405 Store locked up. P501 Dispose of contents/ container to an approved waste disposal plant.
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	Hydrofluoric (HF) acid burns require immediate and specialized first aid and medical treatment. Symptoms may be delayed up to 24 hours depending on the concentration of HF. After decontamination with water, further damage can occur due to penetration/absorption of the fluoride ion. Treatment should be directed toward binding the fluoride ion as well as the effects of exposure. Skin exposures can be treated with a 2.5% calcium gluconate gel repeated until burning ceases. More serious skin exposures may require subcutaneous calcium gluconate except for digital areas unless the physician is experienced in this technique, due to the potential for tissue injury from increased pressure. Absorption can readily
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If inhaled	occur through the subungual areas and should be
Eye Contact	After inhalation: fresh air. Call in physician. After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.
Swallowed	After swallowing: immediately make victim drink water (two glasses at most). Consult a physician
Skin Contact	First treatment with calcium gluconate paste. In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.
Inhalation	Remove patient to fresh air, keep warm and at rest and get medical assistance in necessary.
Ingestion	Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.
Most important symptoms and effects, both acute and delaye	The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11
Indication of any immediate medical attention and special treatment needed	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 (CO <sub>2</sub> ) 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 <sub>x</sub> ) Hydrogen fluoride Calcium oxide 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.
Environmental 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

## 7. Handling and Storage

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Advice on protection against fire and explosion

Work under hood. Do not inhale substance/mixture.

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 precautions see section 2.2.

Advice on safe handling

Work under hood. Do not inhale substance/mixture.

Conditions for safe storage, including any incompatibilities

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.

Storage class

Storage class (TRGS 510): 6.1C: Combustible, acute toxic Cat.3 / toxic compounds or compounds which causing chronic effects

Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

Advice on general occupational hygiene

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 EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://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 P3 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

powder

Colour

white, off-white

Odour	No data available
Odor Threshold	Not Applicable
pH	No data available
Melting Point	156 °C
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	No information available
Incompatible materials	Strong oxidizing agents, Acids, Bases
Hazardous decomposition products	In the event of fire: see section 5

## 11. Toxicological information

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Acute toxicity	LD50 Oral - Rat - > 5.000 mg/kg Inhalation: No data available LD50 Dermal - Rabbit - > 2.000 mg/kg
Skin corrosion/irritation	Skin - Rabbit Result: No skin irritation
Serious eye damage/irritation	Remarks: No data available
Respiratory or skin sensitization	In vivo assay - Guinea pig Does not cause skin sensitization.
Carcinogenicity	No data available
Germ cell mutagenicity	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster lung cells Result: negative Test Type: Ames test Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Result: negative Test Type: Ames test Test system: Escherichia coli Metabolic activation: with and without metabolic activation Result: negative
Reproductive toxicity	Damage to fetus cannot be excluded. Some evidence of adverse effects on development, based on animal experiments.
Specific target organ toxicity - single exposure	No data available
Additional Information	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	No data available
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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Waste treatment Method	No data available
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## 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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