

SAFETY DATA SHEET

Creation Date 05-Apr-2019

Revision Date 24-Dec-2021

Revision Number 2

1. Identification

Product Name Atorvastatin calcium trihydrate

Cat No. : AC464810000, AC464810010, AC464810050

CAS No 344423-98-9
Synonyms No information available

Recommended Use Laboratory chemicals.
Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company
One Reagent Lane
Fair Lawn, NJ 07410
Tel: (201) 796-7100

Acros Organics
One Reagent Lane
Fair Lawn, NJ 07410

Emergency Telephone Number For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99
CHEMTREC Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious Eye Damage/Eye Irritation
Reproductive Toxicity

Category 2
Category 1A

Label Elements

Signal Word

Danger

Hazard Statements

Causes serious eye irritation
May damage fertility or the unborn child

**Precautionary Statements****Prevention**

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Use personal protective equipment as required

Wash face, hands and any exposed skin thoroughly after handling

Wear eye/face protection

Response

IF exposed or concerned: Get medical attention/advice

Eyes

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

Storage

Store locked up

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

None identified

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Atorvastatin calcium trihydrate	344423-98-9	>95
Atorvastatin calcium	134523-03-8	-

4. First-aid measures

General Advice

If symptoms persist, call a physician.

Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

Inhalation

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

Most important symptoms and effects

None reasonably foreseeable.

Notes to Physician

Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the

surrounding environment. Dry chemical, CO₂, water spray or alcohol-resistant foam.

Unsuitable Extinguishing Media No information available

Flash Point No information available
Method - No information available

Autoignition Temperature No information available

Explosion Limits

Upper No data available

Lower No data available

Sensitivity to Mechanical Impact No information available

Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NO_x). Hydrogen fluoride.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

Health
2

Flammability
1

Instability
0

Physical hazards
N/A

6. Accidental release measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Up Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

7. Handling and storage

Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Storage. Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible Materials. Strong oxidizing agents. Acids. Bases.

8. Exposure controls / personal protection

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Engineering Measures Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical State	Solid
Appearance	White
Odor	No information available
Odor Threshold	No information available
pH	No information available
Melting Point/Range	156 °C / 312.8 °F
Boiling Point/Range	No information available
Flash Point	No information available
Evaporation Rate	Not applicable
Flammability (solid,gas)	No information available
Flammability or explosive limits	
Upper	No data available
Lower	No data available
Vapor Pressure	No information available
Vapor Density	Not applicable
Specific Gravity	No information available
Solubility	Insoluble in water
Partition coefficient; n-octanol/water	No data available
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	Not applicable
Molecular Formula	C33 H34 F N2 O5 . 0.5Ca . 1.5H2O
Molecular Weight	604.69

10. Stability and reactivity

Reactive Hazard	None known, based on information available
Stability	Stable under recommended storage conditions.
Conditions to Avoid	Incompatible products.
Incompatible Materials	Strong oxidizing agents, Acids, Bases
Hazardous Decomposition Products	Carbon monoxide (CO), Carbon dioxide (CO ₂), Nitrogen oxides (NO _x), Hydrogen fluoride
Hazardous Polymerization	Hazardous polymerization does not occur.
Hazardous Reactions	None under normal processing.

11. Toxicological information

Acute Toxicity**Product Information****Component Information**

Toxicologically Synergistic Products No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation Irritating to eyes

Sensitization No information available

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Atorvastatin calcium trihydrate	344423-98-9	Not listed	Not listed	Not listed	Not listed	Not listed
Atorvastatin calcium	134523-03-8	Not listed	Not listed	Not listed	Not listed	Not listed

Mutagenic Effects

No information available

Reproductive Effects

No information available.

Developmental Effects

No information available.

Teratogenicity

No information available.

STOT - single exposure

None known

STOT - repeated exposure

None known

Aspiration hazard

No information available

Symptoms / effects, both acute and delayed

No information available

Endocrine Disruptor Information

No information available

Other Adverse Effects

The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability

Insoluble in water

Bioaccumulation/ Accumulation

No information available.

Mobility

Is not likely mobile in the environment due its low water solubility.

13. Disposal considerations

Waste Disposal Methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOT

Not regulated

TDG

Not regulated

IATA

Not regulated

IMDG/IMO

Not regulated

15. Regulatory information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Atorvastatin calcium trihydrate	344423-98-9	-	-	-
Atorvastatin calcium	134523-03-8	-	-	-

Legend:**TSCA** US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Atorvastatin calcium trihydrate	344423-98-9	-	-	-	-	-		-	-	-
Atorvastatin calcium	134523-03-8	-	-	-	-	-		-	X	-

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and Health Administration Not applicable

CERCLA Not applicable

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland Security This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

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

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Atorvastatin calcium trihydrate	344423-98-9	Not applicable	Not applicable	Not applicable	Not applicable
Atorvastatin calcium	134523-03-8	Not applicable	Not applicable	Not applicable	Not applicable

Component	CAS No	Seveso III Directive	Seveso III Directive	Rotterdam	Basel Convention
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		(2012/18/EC) - Qualifying Quantities for Major Accident Notification	(2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Convention (PIC)	(Hazardous Waste)
Atorvastatin calcium trihydrate	344423-98-9	Not applicable	Not applicable	Not applicable	Not applicable
Atorvastatin calcium	134523-03-8	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Prepared By Regulatory Affairs
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Revision Summary Not applicable.

Disclaimer

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End of SDS