# SAFETY DATA SHEET

Version 5.0 Revision Date 01/17/2018 Print Date 11/09/2018

# 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : Atorvastatin Calcium

Product Number : 1044516 Brand : USP

CAS-No. : 344423-98-9

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Synthesis of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich

3050 Spruce Street SAINT LOUIS MO 63103

**USA** 

Telephone : +1 800-325-5832 Fax : +1 800-325-5052

1.4 Emergency telephone number

Emergency Phone # : +1-703-527-3887 (CHEMTREC)

### 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

# GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Eye irritation (Category 2A), H319

Reproductive toxicity (Category 1B), H360

For the full text of the H-Statements mentioned in this Section, see Section 16.

## 2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word Danger

Hazard statement(s)

H319 Causes serious eye irritation.

H360 May damage fertility or the unborn child.

Precautionary statement(s)

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and

understood.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protection/ face

protection.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Get medical advice/ attention.

P308 + P313 IF exposed or concerned: Get medical advice/ attention P337 + P313 If eye irritation persists: Get medical advice/ attention.

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P405 Store locked up.

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

# 2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Formula : C66H68CaF2N4O10 · 3H2O

Molecular weight : 1,209.38 g/mol CAS-No. : 344423-98-9

Hazardous components

| Component | Classification                 | Concentration |
|-----------|--------------------------------|---------------|
|           | Eye Irrit. 2A; Repr. 1B; H319, | 90 - 100 %    |
|           | H360                           |               |

For the full text of the H-Statements mentioned in this Section, see Section 16.

### 4. FIRST AID MEASURES

# 4.1 Description of first aid measures

#### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

#### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

#### In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

# In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

## If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

# 4.2 Most important symptoms and effects, both acute and delayed

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

## 4.3 Indication of any immediate medical attention and special treatment needed

No data available

# 5. FIREFIGHTING MEASURES

# 5.1 Extinguishing media

# Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

### 5.2 Special hazards arising from the substance or mixture

No data available

# 5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

#### 5.4 Further information

No data available

### 6. ACCIDENTAL RELEASE MEASURES

# 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

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For personal protection see section 8.

## 6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

# 6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

For disposal see section 13.

### 7. HANDLING AND STORAGE

## 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

# 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

Storage class (TRGS 510): 6.1D: Non-combustible, acute toxic Cat.3 / toxic hazardous materials or hazardous materials causing chronic effects

#### 7.3 Specific end use(s)

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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

# Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

# 8.2 Exposure controls

### Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

# Personal protective equipment

#### Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

# **Body Protection**

Impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

# Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

# Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

## 9.1 Information on basic physical and chemical properties

a) Appearance Form: Crystalline powder

Colour: white, off-white

b) Odour No data availablec) Odour Threshold No data available

d) pH No data available

e) Melting point/freezing

point

Melting point/range: 156 °C (313 °F)

f) Initial boiling point and

boiling range

No data available

g) Flash point No data available
h) Evaporation rate No data available
i) Flammability (solid, gas) No data available

Upper/lower flammability or explosive limits No data available

k) Vapour pressure No data available
 l) Vapour density No data available
 m) Relative density No data available
 n) Water solubility practically insoluble

 Partition coefficient: noctanol/water No data available

p) Auto-ignition temperature

No data available

q) Decomposition temperature

No data available

r) Viscosity s) Explosive properties

No data available No data available

t) Oxidizing properties

No data available

9.2 Other safety information

Solubility in other

Methanol - soluble

solvents

# 10. STABILITY AND REACTIVITY

# 10.1 Reactivity

No data available

## 10.2 Chemical stability

Stable under recommended storage conditions.

# 10.3 Possibility of hazardous reactions

No data available

# 10.4 Conditions to avoid

No data available

# 10.5 Incompatible materials

Strong oxidizing agents, Acids, Bases

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### 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx), Hydrogen fluoride, Calcium oxide

In the event of fire: see section 5

### 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

# **Acute toxicity**

LD50 Oral - Rat - > 5,000 mg/kg

LD50 Oral - Mouse - > 5,000 mg/kg

Inhalation: No data available

LD50 Dermal - Rabbit - > 2,000 mg/kg

No data available

#### Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation

# Serious eye damage/eye irritation

Eyes - Rabbit

Result: Irritating to eyes.

### Respiratory or skin sensitisation

in vivo assay - Guinea pig

Does not cause skin sensitisation.

### Germ cell mutagenicity

Result: Not mutagenic in Ames Test

Chromosome aberration test in vitro

Chinese hamster lung cells

Result: negative

# Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as

probable, possible or confirmed human carcinogen by IARC.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a

known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's

list of regulated carcinogens.

## Reproductive toxicity

Damage to fetus cannot be excluded. Some evidence of adverse effects on development, based on animal experiments.

No data available

# Specific target organ toxicity - single exposure

No data available

# Specific target organ toxicity - repeated exposure

No data available

# **Aspiration hazard**

No data available

#### **Additional Information**

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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# 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity

No data available

## 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

# 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

#### 12.6 Other adverse effects

No data available

# 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

#### Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

# Contaminated packaging

Dispose of as unused product.

# 14. TRANSPORT INFORMATION

# DOT (US)

Not dangerous goods

### **IMDG**

Not dangerous goods

#### **IATA**

Not dangerous goods

# 15. REGULATORY INFORMATION

# **SARA 302 Components**

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

#### **SARA 313 Components**

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### SARA 311/312 Hazards

Chronic Health Hazard

# **Massachusetts Right To Know Components**

No components are subject to the Massachusetts Right to Know Act.

# Pennsylvania Right To Know Components

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### **New Jersey Right To Know Components**

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**Revision Date** 

### California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### 16. OTHER INFORMATION

### Full text of H-Statements referred to under sections 2 and 3.

Eye Irrit. Eye irritation

H319 Causes serious eye irritation.

H360 May damage fertility or the unborn child.

Repr. Reproductive toxicity

**HMIS Rating** 

Health hazard: 0
Chronic Health Hazard: \*
Flammability: 0
Physical Hazard 0

NFPA Rating

Health hazard: 0
Fire Hazard: 0
Reactivity Hazard: 0

### **Further information**

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### **Preparation Information**

Sigma-Aldrich Corporation Product Safety – Americas Region 1-800-521-8956

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