

## Atorvastatin Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 03/23/2020  
6.3                10/10/2020                184708-00011            Date of first issue: 06/17/2015

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### SECTION 1. IDENTIFICATION

Product name                                : Atorvastatin Formulation

#### Manufacturer or supplier's details

Company name of supplier                : Merck & Co., Inc  
Address                                        : 126 E. Lincoln Avenue  
    : Rahway, New Jersey U.S.A 07065  
Telephone                                    : 908-740-4000  
Emergency telephone                      : 1-908-423-6000  
E-mail address                              : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use                          : Pharmaceutical

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Specific target organ toxicity            : Category 2 (Liver, muscle)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms                        :



Signal Word                                : Warning

Hazard Statements                        : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H373 May cause damage to organs (Liver, muscle) through prolonged or repeated exposure if swallowed.

Precautionary Statements                : **Prevention:**  
P260 Do not breathe dust.  
**Response:**  
P314 Get medical attention if you feel unwell.  
**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

#### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

| Chemical name     | CAS-No.     | Concentration (% w/w) |
|-------------------|-------------|-----------------------|
| Calcium carbonate | 471-34-1    | >= 30 - < 50          |
| Cellulose         | 9004-34-6   | >= 20 - < 30          |
| Atorvastatin      | 134523-03-8 | >= 10 - < 20          |

Actual concentration is withheld as a trade secret

### 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.  
 Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap.  
 Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
 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 damage to organs through prolonged or repeated exposure if swallowed.  
 Contact with dust can cause mechanical irritation or drying of the skin.  
 Dust contact with the eyes can lead to mechanical irritation.
- 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. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
 Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
 Nitrogen oxides (NO<sub>x</sub>)  
 Fluorine compounds  
 Metal oxides

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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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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### 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.  
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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.

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### SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.  
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  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.

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Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
 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

#### Ingredients with workplace control parameters

| Components        | CAS-No.     | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis     |
|-------------------|-------------|-------------------------------|--|-----------|
| Calcium carbonate | 471-34-1    | TWA (Respirable)              | 5 mg/m <sup>3</sup> (Calcium carbonate)        | NIOSH REL |
|                   |             | TWA (total)                   | 10 mg/m <sup>3</sup> (Calcium carbonate)       | NIOSH REL |
| Cellulose         | 9004-34-6   | TWA                           | 10 mg/m <sup>3</sup>                           | ACGIH     |
|                   |             | TWA (Respirable)              | 5 mg/m <sup>3</sup>                            | NIOSH REL |
|                   |             | TWA (total)                   | 10 mg/m <sup>3</sup>                           | NIOSH REL |
|                   |             | TWA (total dust)              | 15 mg/m <sup>3</sup>                           | OSHA Z-1  |
|                   |             | TWA (respirable fraction)     | 5 mg/m <sup>3</sup>                            | OSHA Z-1  |
| Atorvastatin      | 134523-03-8 | TWA                           | 0.05 mg/m <sup>3</sup> (OEB 3)                 | Internal  |
|                   |             | Wipe limit                    | 0.5 mg/100 cm <sup>2</sup>                     | Internal  |

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
 Minimize open handling.

#### Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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### Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : granular

Color : No data available

Odor : No data available

Odor 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) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper : No data available

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flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition 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

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

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**Acute toxicity**

Not classified based on available information.

**Components:****Calcium carbonate:**

- Acute oral toxicity                    : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 420  
Assessment: The substance or mixture has no acute oral toxicity
- Acute inhalation toxicity            : LC50 (Rat): > 3 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity
- Acute dermal toxicity                : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

**Cellulose:**

- Acute oral toxicity                    : LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity            : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist
- Acute dermal toxicity                : LD50 (Rabbit): > 2,000 mg/kg

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- Acute oral toxicity                    : LD50 (Rat, male and female): > 5,000 mg/kg  
LD50 (Mouse, male and female): > 5,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Calcium carbonate:**

- Species                                : Rabbit  
Method                                 : OECD Test Guideline 404  
Result                                  : No skin irritation

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- Species                                : Rabbit  
Result                                  : No skin irritation

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**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Calcium carbonate:**

Species                                : Rabbit  
Result                                 : No eye irritation  
Method                                 : OECD Test Guideline 405

**Atorvastatin:**

Species                                : Rabbit  
Result                                 : No eye irritation  
Method                                 : Draize Test

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Calcium carbonate:**

Test Type                               : Local lymph node assay (LLNA)  
Routes of exposure                    : Skin contact  
Species                                 : Mouse  
Method                                 : OECD Test Guideline 429  
Result                                 : negative

**Atorvastatin:**

Test Type                               : Maximization Test  
Routes of exposure                    : Skin contact  
Species                                 : Guinea pig  
Result                                 : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Calcium carbonate:**

Genotoxicity in vitro                : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476



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Result: negative

### Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

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Genotoxicity in vitro : Test Type: reverse mutation assay  
Test system: Salmonella typhimurium  
Result: negative

Test Type: reverse mutation assay  
Test system: Escherichia coli  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster lung cells  
Result: negative

Test Type: sister chromatid exchange assay  
Test system: Chinese hamster lung cells  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### Cellulose:

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

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Species : Mouse, male and female  
Application Route : oral (gavage)

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Exposure time : 2 Years  
 NOAEL : 200 mg/kg body weight  
 LOAEL : 400 mg/kg body weight  
 Result : negative  
 Target Organs : Liver

Species : Rat, female  
 Application Route : oral (gavage)  
 Exposure time : 2 Years  
 LOAEL : 100 mg/kg body weight  
 Target Organs : Musculo-skeletal system

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Not classified based on available information.

### Components:

#### **Calcium carbonate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 414  
 Result: negative

#### **Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

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Effects on fertility : Test Type: Fertility/early embryonic development

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Species: Rat, female  
 Fertility: NOAEL: 225 mg/kg body weight  
 Result: No effects on fertility.

Test Type: Fertility/early embryonic development  
 Species: Rat, male  
 Fertility: NOAEL: 175 mg/kg body weight  
 Result: No effects on fertility.

Effects on fetal development : Species: Rat, female  
 Developmental Toxicity: NOAEL: 20 mg/kg body weight  
 Result: No teratogenic effects., Embryo-fetal toxicity.  
 Remarks: Maternal toxicity observed.

Species: Rabbit, female  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 100 mg/kg body weight  
 Result: No embryo-fetal toxicity.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

May cause damage to organs (Liver, muscle) through prolonged or repeated exposure if swallowed.

### Components:

#### Atorvastatin:

Routes of exposure : Ingestion  
 Target Organs : Liver, muscle  
 Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Calcium carbonate:

Species : Rat  
 NOAEL : > 1,000 mg/kg  
 Application Route : Ingestion  
 Exposure time : 28 Days  
 Method : OECD Test Guideline 422

#### Cellulose:

Species : Rat  
 NOAEL : >= 9,000 mg/kg  
 Application Route : Ingestion  
 Exposure time : 90 Days

#### Atorvastatin:

Species : Rat, male and female

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LOAEL : 70 mg/kg  
 Application Route : oral (gavage)  
 Exposure time : 52 Weeks  
 Target Organs : Liver

Species : Dog  
 LOAEL : 10 mg/kg  
 Application Route : oral (gavage)  
 Exposure time : 104 Weeks  
 Target Organs : Liver

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Atorvastatin:

Ingestion : Symptoms: muscle pain, Fatigue, stomach discomfort, Abdominal pain, constipation, flatulence, liver function change

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Calcium carbonate:

Toxicity to fish : LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
 Exposure time: 96 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 100 mg/l  
 Exposure time: 48 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : NOELR (Pseudokirchneriella subcapitata (green algae)): 50 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC: 1,000 mg/l  
 Exposure time: 3 h  
 Method: OECD Test Guideline 209

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EC50: > 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

**Cellulose:**

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

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Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): > 92 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 200 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (green algae)): 108 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (*Pseudokirchneriella subcapitata* (green algae)): 14 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (*Pimephales promelas* (fathead minnow)): 0.49 mg/l  
Exposure time: 33 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 0.2 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

**Persistence and degradability****Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

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Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 7.7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

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### Bioaccumulative potential

#### Components:

##### Atorvastatin:

Partition coefficient: n-octanol/water : log Pow: 1.62

### Mobility in soil

#### Components:

##### Atorvastatin:

Distribution among environmental compartments : log Koc: 2.84

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
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.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

Not regulated as a dangerous good

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## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

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**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust  
Specific target organ toxicity (single or repeated exposure)

**SARA 313** : 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.

**US State Regulations****Pennsylvania Right To Know**

|  |             |
|--|-------------|
| Calcium carbonate                                      | 471-34-1    |
| D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate | 64044-51-5  |
| Cellulose  | 9004-34-6   |
| Atorvastatin   | 134523-03-8 |
| Croscarmellose sodium                                  | 74811-65-7  |

**California Permissible Exposure Limits for Chemical Contaminants**

|                   |           |
|-------------------|-----------|
| Calcium carbonate | 471-34-1  |
| Cellulose         | 9004-34-6 |

**The ingredients of this product are reported in the following inventories:**

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

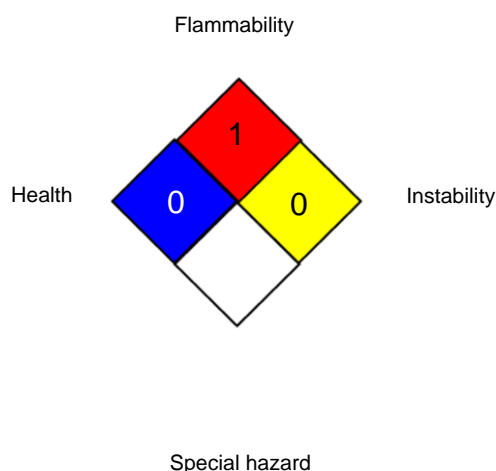
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**SECTION 16. OTHER INFORMATION****Further information**

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## NFPA 704:



## HMIS® IV:

|                        |   |          |
|------------------------|---|----------|
| <b>HEALTH</b>          | * | <b>2</b> |
| <b>FLAMMABILITY</b>    |   | <b>3</b> |
| <b>PHYSICAL HAZARD</b> |   | <b>0</b> |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

## Full text of other abbreviations

|                 |   |   |
|-----------------|---|---|
| ACGIH           | : | USA. ACGIH Threshold Limit Values (TLV)   |
| NIOSH REL       | : | USA. NIOSH Recommended Exposure Limits  |
| OSHA Z-1        | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants          |
| ACGIH / TWA     | : | 8-hour, time-weighted average   |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| OSHA Z-1 / TWA  | : | 8-hour time weighted average  |

AIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; KECI - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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)



**Atorvastatin Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 03/23/2020  |
| 6.3     | 10/10/2020     | 184708-00011 | Date of first issue: 06/17/2015 |

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tative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 10/10/2020

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.

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