

# SAFETY DATA SHEET



## Simvastatin Formulation



Version 8.2      Revision Date: 06.04.2024      SDS Number: 24373-00023      Date of last issue: 26.09.2023  
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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Simvastatin Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : Avenida 16 de Septiembre No. 301  
Xaltocan - Xochimilco Mexico 16090  
Telephone : +52 55 57284444  
Emergency telephone : 1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Skin corrosion/irritation : Category 3  
Skin sensitization : Category 1  
Carcinogenicity (Inhalation) : Category 2  
Specific target organ toxicity - repeated exposure : Category 1 (Liver, muscle, optic nerve, Eye)

#### GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H316 Causes mild skin irritation.  
H317 May cause an allergic skin reaction.  
H351 Suspected of causing cancer if inhaled.  
H372 Causes damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P272 Contaminated work clothing should not be allowed out of the workplace.

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

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
 P362 + P364 Take off contaminated clothing and wash it before reuse.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

Dust contact with the eyes can lead to mechanical irritation.  
 May form explosive dust-air mixture during processing, handling or other means.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Simvastatin	79902-63-9	>= 5 -< 10
Starch	9005-25-8	>= 5 -< 10
Cellulose	9004-34-6	>= 1 -< 5
Ascorbic acid	50-81-7	>= 1 -< 5
Citric acid monohydrate	5949-29-1	>= 1 -< 5
Titanium dioxide	13463-67-7	>= 0.1 -< 1

**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.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
 Remove contaminated clothing and shoes.  
 Get medical attention.  
 Wash clothing before reuse.  
 Thoroughly clean shoes before reuse.

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.

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Most important symptoms and effects, both acute and delayed	:	Causes mild skin irritation. May cause an allergic skin reaction. Suspected of causing cancer if inhaled. Causes damage to organs through prolonged or repeated exposure. 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.

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### 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
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

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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.<br>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 get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures            | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>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.   |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store in accordance with the particular national regulations.  |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases   |

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Simvastatin	79902-63-9	TWA	25 µg/m <sup>3</sup> (OEB 3)	Internal
	Further information: DSEN			
		Wipe limit	250 µg/100 cm <sup>2</sup>	Internal
Starch	9005-25-8	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Cellulose	9004-34-6	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Ascorbic acid	50-81-7	TWA	5000 µg/m <sup>3</sup> (OEB 1)	Internal
Titanium dioxide	13463-67-7	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014

**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 : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

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Appearance : powder

Color : No data available

Odor : odorless

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 : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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Particle characteristics  
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

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Simvastatin:

Acute oral toxicity : LD50 (Rat): 5,000 mg/kg  
LD50 (Mouse): 3,800 mg/kg

##### Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### 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

##### Ascorbic acid:

Acute oral toxicity : LD50 (Rat): 11,900 mg/kg

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### **Citric acid monohydrate:**

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

### **Titanium dioxide:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

### **Skin corrosion/irritation**

Causes mild skin irritation.

### **Components:**

#### **Simvastatin:**

Species : Rabbit  
Remarks : Moderate skin irritation

#### **Ascorbic acid:**

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

#### **Citric acid monohydrate:**

Species : Rabbit  
Result : No skin irritation

#### **Titanium dioxide:**

Species : Rabbit  
Result : No skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Simvastatin:**

Species : Rabbit  
Remarks : slight irritation



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**Starch:**

Species	:	Rabbit
Result	:	No eye irritation

**Ascorbic acid:**

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

**Citric acid monohydrate:**

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days

**Titanium dioxide:**

Species	:	Rabbit
Result	:	No eye irritation

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

May cause an allergic skin reaction.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Simvastatin:**

Assessment	:	Probability or evidence of skin sensitization in humans
Result	:	positive

**Starch:**

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

**Ascorbic acid:**

Test Type	:	Maurer optimisation test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

**Titanium dioxide:**

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

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### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Simvastatin:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: Alkaline elution assay  
Result: negative
- Test Type: Chromosomal aberration  
Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
Result: negative
- Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: negative
- Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

#### **Starch:**

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

#### **Ascorbic acid:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Result: negative

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

### **Citric acid monohydrate:**

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

Test Type: in vitro micronucleus test  
Result: positive

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **Titanium dioxide:**

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

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Result: negative

### **Carcinogenicity**

Suspected of causing cancer if inhaled.

### **Components:**

#### **Simvastatin:**

Species : Mouse  
Application Route : Oral  
Exposure time : < 92 weeks  
Target Organs : Harderian gland  
Tumor Type : Liver, Lungs  
Remarks : The significance of these findings for humans is not certain.

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Tumor Type : Liver, Thyroid  
Remarks : The significance of these findings for humans is not certain.

#### **Cellulose:**

Species : Rat  
Application Route : Ingestion

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Exposure time : 72 weeks  
Result : negative

**Ascorbic acid:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

**Titanium dioxide:**

Species : Rat  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : positive  
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Simvastatin:**

Effects on fertility : Test Type: Fertility  
Species: Rat, male  
Application Route: Oral  
Fertility: LOAEL: 25 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: NOAEL: 25 mg/kg body weight  
Result: No teratogenic effects., No adverse effects.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-fetal toxicity.: NOAEL: 10 mg/kg body weight  
Result: No teratogenic effects., No adverse effects.

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: LOAEL: 60 mg/kg body weight  
Result: Teratogenic potential.  
Remarks: Based on data from similar materials

**Cellulose:**

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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

### Ascorbic acid:

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

### Citric acid monohydrate:

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

### STOT-single exposure

Not classified based on available information.

### Components:

#### Citric acid monohydrate:

Assessment : May cause respiratory irritation.

### STOT-repeated exposure

Causes damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

### Components:

#### Simvastatin:

Target Organs : Liver, muscle, optic nerve, Eye  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Simvastatin:

Species : Rat  
NOAEL : 5 mg/kg  
LOAEL : 30 mg/kg  
Application Route : Oral  
Exposure time : 14 - 104 Weeks  
Target Organs : Liver, Testis, Musculo-skeletal system, Eye

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Species : Dog  
LOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 14 - 104 Weeks  
Target Organs : Liver, Testis, Eye

Species : Rabbit  
NOAEL : 30 mg/kg  
LOAEL : 50 mg/kg  
Application Route : Oral  
Target Organs : Liver, Kidney

**Starch:**

Species : Rat  
NOAEL :  $\geq 2,000$  mg/kg  
Application Route : Skin contact  
Exposure time : 28 Days  
Method : OECD Test Guideline 410

**Cellulose:**

Species : Rat  
NOAEL :  $\geq 9,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

**Ascorbic acid:**

Species : Rat, male  
NOAEL :  $\geq 8,100$  mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks

**Citric acid monohydrate:**

Species : Rat  
NOAEL : 4,000 mg/kg  
LOAEL : 8,000 mg/kg  
Application Route : Ingestion  
Exposure time : 10 Days

**Titanium dioxide:**

Species : Rat  
NOAEL : 24,000 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days

Species : Rat  
NOAEL : 10 mg/m<sup>3</sup>  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 y

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### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Simvastatin:

Skin contact : Remarks: May produce an allergic reaction.  
Ingestion : Target Organs: Liver  
Symptoms: upper respiratory tract infection, Headache, Abdominal pain, constipation, Nausea  
Target Organs: Musculo-skeletal system

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Simvastatin:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2.91 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 3.5 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 25  
plants : mg/l  
Exposure time: 96 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 25  
mg/l  
Exposure time: 96 h

Toxicity to microorganisms : EC50: > 30 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 21 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
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

#### Ascorbic acid:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l

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Toxicity to microorganisms : Exposure time: 96 h  
Method: OECD Test Guideline 203  
: EC50: 140 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8

### **Citric acid monohydrate:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,535 mg/l  
Exposure time: 24 h

### **Titanium dioxide:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l  
Exposure time: 72 h  
Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

### **Persistence and degradability**

#### **Components:**

##### **Simvastatin:**

Biodegradability : Result: rapidly degradable  
Stability in water : Hydrolysis: 50 %(3.2 d)

##### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

##### **Ascorbic acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 5 d  
Method: OECD Test Guideline 302

##### **Citric acid monohydrate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d



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Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Components:

##### **Simvastatin:**

Partition coefficient: n-octanol/water : log Pow: > 4.07

##### **Ascorbic acid:**

Partition coefficient: n-octanol/water : log Pow: -1.85

##### **Citric acid monohydrate:**

Partition coefficient: n-octanol/water : log Pow: -1.72

#### **Mobility in soil**

No data available

#### **Other adverse effects**

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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**

#### **NOM-002-SCT**

Not regulated as a dangerous good

#### **Special precautions for user**

Not applicable

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

Revision Date : 06.04.2024  
Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits  
ACGIH / TWA : 8-hour, time-weighted average  
NOM-010-STPS-2014 / VLE- : Time weighted average limit value  
PPT

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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

# SAFETY DATA SHEET



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es; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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/>

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8