

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Simvastatin Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

Emergency telephone number : +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

---

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Skin corrosion/irritation : Category 3

Skin sensitisation : Category 1

Specific target organ toxicity - repeated exposure : Category 2 (Liver, muscle, optic nerve, Eye)

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 3

##### GHS label elements

Hazard pictograms :

Signal word : Warning

---

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

Hazard statements : H316 Causes mild skin irritation.  
H317 May cause an allergic skin reaction.  
H373 May cause damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P260 Do not breathe dust.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P273 Avoid release to the environment.  
P280 Wear protective gloves.  
**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of water.  
P319 Get medical help if you feel unwell.  
P333 + P317 If skin irritation or rash occurs: Get medical help.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

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

## 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

## 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.0	06.04.2024	24368-00023	Date of first issue: 21.10.2014

---

In case of eye contact	:	Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. If in eyes, rinse well with water.
If swallowed	:	Get medical attention if irritation develops and persists. 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	:	Causes mild skin irritation. May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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.

---

### 5. FIREFIGHTING 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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

---

### 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

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.

### 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 get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
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.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	ACGIH
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Ascorbic acid	50-81-7	TWA	5000 µg/m <sup>3</sup> (OEB 1)	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** : 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.

**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.  
Contaminated work clothing should not be allowed out of the workplace.  
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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : powder

**Colour** : No data available

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.0	06.04.2024	24368-00023	Date of first issue: 21.10.2014

---

Odour	:	odourless
Odour 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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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.
Particle characteristics Particle size	:	No data available

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

### 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.

### 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

##### Citric acid monohydrate:

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

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

#### Starch:

Species : Rabbit  
Result : No eye irritation



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

### Ascorbic acid:

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

### Citric acid monohydrate:

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

### Titanium dioxide:

Species : Rabbit  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Simvastatin:

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

#### Starch:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

#### Ascorbic acid:

Test Type : Maurer optimisation test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

#### Titanium dioxide:

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version  
7.0

Revision Date:  
06.04.2024

SDS Number:  
24368-00023

Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

### 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
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

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

Not classified based on available information.

### 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

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

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

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

### Cellulose:

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

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

### Ascorbic acid:

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

### Citric acid monohydrate:

Effects on foetal development : Test Type: Embryo-foetal 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

May cause 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

|| Target Organs : Liver, Testis, Musculo-skeletal system, Eye

|| 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 yr

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

### 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

## 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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.5 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 ( Pseudokirchneriella subcapitata (green algae)): > 25 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 24368-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

### Ascorbic acid:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to microorganisms : 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



# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.0	06.04.2024	24368-00023	Date of first issue: 21.10.2014

---

### Citric acid monohydrate:

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

---

## 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.

---

## 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 IMO instruments

Not applicable for product as supplied.

---

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.0	06.04.2024	24368-00023	Date of first issue: 21.10.2014

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

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

#### The components of this product are reported in the following inventories:

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

## 16. OTHER INFORMATION

Revision Date : 06.04.2024

### Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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; KECl - 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.0	06.04.2024	24368-00023	Date of first issue: 21.10.2014

---

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) 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

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.

IN / EN