

# SAFETY DATA SHEET



## Simvastatin Formulation



Version 7.2      Revision Date: 06.04.2024      SDS Number: 24348-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

### SECTION 1: 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

---

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Skin sensitisation : Category 1

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

#### GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.  
H373 May cause damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P260 Do not breathe dust.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves.

**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of water.

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

P314 Get medical advice/ attention if you feel unwell.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
 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.

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

Substance / Mixture : Mixture

**Components**

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

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.  
 May cause 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

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

Notes to physician : when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

---

**SECTION 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.

---

**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

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

certain local or national requirements.

---

**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 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.
- 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.
- 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

---

**SECTION 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



## Simvastatin Formulation



Version 7.2      Revision Date: 06.04.2024      SDS Number: 24348-00023      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>	AU OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	AU OEL
		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	TWA	10 mg/m <sup>3</sup>	AU OEL

**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

Appearance : powder  
Colour : No data available  
Odour : odourless  
Odour Threshold : No data available  
pH : No data available

# SAFETY DATA SHEET



## Simvastatin Formulation



Version 7.2      Revision Date: 06.04.2024      SDS Number: 24348-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

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

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

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.

---

**SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes	:	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:**

Acute oral toxicity	:	LD50 (Mouse): 5,400 mg/kg
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402

## Simvastatin Formulation

Version 7.2      Revision Date: 06.04.2024      SDS Number: 24348-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

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**

Not classified based on available information.

**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



## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

**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 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

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

**Chronic toxicity****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

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

Test Type: Chromosome aberration test in vitro  
Result: negative

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**

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

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

Remarks : The significance of these findings for humans is not certain.

**Cellulose:**

Species : Rat  
 Application Route : Ingestion  
 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

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

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

**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.

## Simvastatin Formulation

Version 7.2      Revision Date: 06.04.2024      SDS Number: 24348-00023      Date of last issue: 26.09.2023  
Date of first issue: 21.10.2014

---

**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

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

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

**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

**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

**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 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

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

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  
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



# SAFETY DATA SHEET



## Simvastatin Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

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  
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

---

## 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.

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

##### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

##### IMDG-Code

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

#### National Regulations

##### ADG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

#### Special precautions for user

Not applicable

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

---

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

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

**SECTION 16: ANY OTHER RELEVANT INFORMATION****Further information**

Revision Date : 06.04.2024  
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/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - 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 con-

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
7.2	06.04.2024	24348-00023	Date of first issue: 21.10.2014

---

centration; 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; (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.

AU / EN