

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Simvastatin Formulation

Version 3.3      Revision Date: 23.03.2020      SDS Number: 24364-00015      Date of last issue: 13.09.2019  
Date of first issue: 21.10.2014

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Simvastatin Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

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P260 Do not breathe dust.  
P273 Avoid release to the environment.  
P280 Wear protective gloves.

### Response:

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.

### Hazardous components which must be listed on the label:

Simvastatin

### 2.3 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

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Simvastatin	79902-63-9	Skin Irrit. 2; H315 Skin Sens. 1; H317 STOT RE 1; H372 Aquatic Chronic 2; H411	$\geq 2.5 - < 10$
Citric acid monohydrate	5949-29-1	Eye Irrit. 2; H319	$\geq 1 - < 10$

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of 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.
- 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).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

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- 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.

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

- Risks : 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.

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

- Treatment : Treat symptomatically and supportively.
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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

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

- 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

### 5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.

#### 6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.  
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.

#### 6.3 Methods and material for containment and cleaning up

Methods for 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.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

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.  
Handle in accordance with good industrial hygiene and safety

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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.  
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. 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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	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	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols, The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m <sup>-3</sup> 8-hour TWA of inhalable dust or 4 mg.m <sup>-3</sup> 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts		

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		have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with., Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.		
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols, The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m <sup>-3</sup> 8-hour TWA of inhalable dust or 4 mg.m <sup>-3</sup> 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.		
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40
		STEL (inhalable dust)	20 mg/m <sup>3</sup>	GB EH40

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Citric acid monohydrate	Fresh water	0.44 mg/l
	Marine water	0.044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34.6 mg/kg dry weight (d.w.)
	Marine sediment	3.46 mg/kg dry weight (d.w.)

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	Soil	33.1 mg/kg dry weight (d.w.)
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### 8.2 Exposure controls

#### 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

- 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.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to BS EN 143
- Filter type : Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : powder
- Colour : No data available
- 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

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

### 9.2 Other information

Flammability (liquids)	:	No data available
Particle size	:	No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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### 10.4 Conditions to avoid



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

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

##### 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

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Simvastatin:

Species : Rabbit  
Remarks : Moderate skin irritation

##### Citric acid monohydrate:

Species : Rabbit  
Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

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### Components:

#### **Simvastatin:**

Species : Rabbit  
Remarks : slight irritation

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

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

### **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

### **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.

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

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

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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

### 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.

### 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

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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

### 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.

### STOT - repeated exposure

May cause damage to organs 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

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

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### Citric acid monohydrate:

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

### 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

### 12.1 Toxicity

#### 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

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### 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

### 12.2 Persistence and degradability

#### Components:

##### Simvastatin:

Biodegradability : Result: rapidly degradable

Stability in water : Hydrolysis: 50 %(3.2 d)

##### Citric acid monohydrate:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### 12.3 Bioaccumulative potential

#### Components:

##### Simvastatin:

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

##### Citric acid monohydrate:

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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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.

### SECTION 14: Transport information

#### 14.1 UN number

Not regulated as a dangerous good

#### 14.2 UN proper shipping name

Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

#### 14.4 Packing group

Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

#### 14.6 Special precautions for user

Not applicable

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

### SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

#### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

### Full text of H-Statements

H315 : Causes skin irritation.

H317 : May cause an allergic skin reaction.

H319 : Causes serious eye irritation.

H372 : Causes damage to organs through prolonged or repeated exposure.

H411 : Toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Skin Irrit. : Skin irritation

Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure

GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
3.3	23.03.2020	24364-00015	Date of first issue: 21.10.2014

Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

Skin Sens. 1	H317
STOT RE 2	H373
Aquatic Chronic 3	H412

### Classification procedure:

Calculation method
Calculation method
Calculation method

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.

GB / EN