

SAFETY DATA SHEET



Simvastatin Formulation



Version 5.0 Revision Date: 2020/03/23 SDS Number: 24371-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Simvastatin Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

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

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use


Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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

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.
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.

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P273 Avoid release to the environment.

P280 Wear protective gloves.

Response:

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

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

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.
lines of the emergency as- : May form explosive dust-air mixture during processing, han-
sumed : dling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Simvastatin	79902-63-9	$\geq 2.5 - < 10$	
Starch	9005-25-8	$\geq 1 - < 10$	8-98
Cellulose	9004-34-6	$\geq 1 - < 10$	
Citric acid monohydrate	5949-29-1	$\geq 1 - < 10$	2-1318
Titanium dioxide	13463-67-7	$\geq 0.1 - < 1$	1-558, 5-5225

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.

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Most important symptoms and effects, both acute and delayed : Rinse mouth thoroughly with water.
: 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 (CO₂)
: 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 and personal protective equipment recommendations.

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.

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 dis-

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posal 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

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 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.
- Avoidance of contact : Oxidizing agents
- 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.

Storage

- 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
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
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		exposure)	concentration	
Simvastatin	79902-63-9	TWA	25 µg/m ³ (OEB 3)	Internal
	Further information: DSEN			
		Wipe limit	250 µg/100 cm ²	Internal
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
Titanium dioxide	13463-67-7	OEL-M (Respirable dust)	1 mg/m ³ (Titanium)	JP OEL JSOH
	Further information: Class 2 Dust			
		OEL-M (Total dust)	4 mg/m ³ (Titanium)	JP OEL JSOH
	Further information: Class 2 Dust			
		TWA	10 mg/m ³ (Titanium dioxide)	ACGIH

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : No data available

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Odour : odourless

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

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

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Particle characteristics

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Particle size : No data available

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

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

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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

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

Citric acid monohydrate:

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

Titanium dioxide:

Species : Rabbit
 Result : No eye irritation

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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

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.

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:

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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
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.

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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
 Exposure time : 72 weeks
 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

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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

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 (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

Components:**Simvastatin:**

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

Repeated dose toxicity**Components:****Simvastatin:**

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

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

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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

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/m³
 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

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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

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

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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

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.

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

Citric acid monohydrate:

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

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Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

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Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Number	Concentration (%)
Titanium(IV) oxide	191	≥ 0.1 - < 1

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Not classified as marine pollutant

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Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION**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 : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

AICS - Australian Inventory of Chemical Substances; 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

SAFETY DATA SHEET



Simvastatin Formulation



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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; 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

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JP / EN