

SAFETY DATA SHEET



Simvastatin Formulation



Version 4.6 Revision Date: 2020/03/23 SDS Number: 24365-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Simvastatin Formulation

Manufacturer or supplier's details

Company : Organon & Co.
Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone : 551-430-6000
Emergency telephone number : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitisation : Category 1
Specific target organ toxicity - repeated exposure : Category 2 (Liver, muscle, optic nerve, Eye)
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.
P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:

Simvastatin Formulation

Version 4.6 Revision Date: 2020/03/23 SDS Number: 24365-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

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

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Simvastatin	79902-63-9	>= 2.5 -< 10
Starch	9005-25-8	< 10
Cellulose	9004-34-6	< 10
Citric acid monohydrate	5949-29-1	< 10
Titanium dioxide	13463-67-7	< 1

4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
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 when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SAFETY DATA SHEET



Simvastatin Formulation



Version 4.6 Revision Date: 2020/03/23 SDS Number: 24365-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

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 disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
-

7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust
-

Simvastatin Formulation

Version 4.6 Revision Date: 2020/03/23 SDS Number: 24365-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

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.

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Simvastatin	79902-63-9	TWA	25 µg/m ³ (OEB 3)	Internal
	Further information: DSEN			
		Wipe limit	250 µg/100 cm ²	Internal
Starch	9005-25-8	NAB	10 mg/m ³	ID OEL
	Further information: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA	10 mg/m ³	ACGIH
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
Titanium dioxide	13463-67-7	NAB	10 mg/m ³	ID OEL
	Further information: Chemicals with a limit value higher than the Allowable Exposure Limit (PEL) of OSHA and/or the recommended NIOSH limit value, Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals, Chemical substance identity issued by other sources, and categorized as suspected of being a human carcinogen.			
		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

SAFETY DATA SHEET



Simvastatin Formulation



Version 4.6 Revision Date: 2020/03/23 SDS Number: 24365-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Colour : No data available
- 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

SAFETY DATA SHEET



Simvastatin Formulation



Version 4.6 Revision Date: 2020/03/23 SDS Number: 24365-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

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 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	:	No hazardous decomposition products are known.

Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
4.6	2020/03/23	24365-00015	Date of first issue: 2014/10/21

products

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
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.

Simvastatin Formulation

Version 4.6 Revision Date: 2020/03/23 SDS Number: 24365-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

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

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

Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
4.6	2020/03/23	24365-00015	Date of first issue: 2014/10/21

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:

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

Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
4.6	2020/03/23	24365-00015	Date of first issue: 2014/10/21

Application Route: Ingestion

Result: negative

Citric acid monohydrate:

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

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

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

Titanium dioxide:

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

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

Carcinogenicity

Not classified based on available information.

Components:**Simvastatin:**

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

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

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
4.6	2020/03/23	24365-00015	Date of first issue: 2014/10/21

Titanium dioxide:

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

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

Reproductive toxicity

Not classified based on available information.

Components:**Simvastatin:**

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

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

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

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

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

Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
4.6	2020/03/23	24365-00015	Date of first issue: 2014/10/21

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
 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

SAFETY DATA SHEET



Simvastatin Formulation



Version Revision Date: SDS Number: Date of last issue: 2019/09/13
4.6 2020/03/23 24365-00015 Date of first issue: 2014/10/21

NOAEL : >= 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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Simvastatin:

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

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

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

Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
4.6	2020/03/23	24365-00015	Date of first issue: 2014/10/21

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

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)

Simvastatin Formulation

Version 4.6 Revision Date: 2020/03/23 SDS Number: 24365-00015 Date of last issue: 2019/09/13
Date of first issue: 2014/10/21

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

Mobility in soil

No data available

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.

Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
4.6	2020/03/23	24365-00015	Date of first issue: 2014/10/21

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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/>

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ID OEL : Indonesia. Occupational Exposure Limits

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

ID OEL / NAB : Long term exposure limit

SAFETY DATA SHEET



Simvastatin Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
4.6	2020/03/23	24365-00015	Date of first issue: 2014/10/21

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; 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; 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.

ID / EN