

Product Name:
Issued:

Simcor Tablets
Mar-10-2014



SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Simcor Tablets

Synonyms: Niacin and Simvastatin Tablets: Simcor Tablets (Niacin Extended Release/Simvastatin); Simcor Tablets (Niacin ER 500 mg/Simvastatin 20 mg); Simcor Tablets (Niacin ER 750 mg/Simvastatin 20 mg); Simcor Tablets (Niacin ER 1000 mg/Simvastatin 20 mg); Simcor Tablets (Niacin ER 1000 mg/Simvastatin 40 mg); Simcor Tablets (Niacin ER 500 mg/Simvastatin 40 mg)

Trade name: Simcor

List Number: 3312; 3315; 3316; 3455; 3457; 3459; 10518; 10519

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-800-255-5162
+1-847-932-7900

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

General Note AbbVie

Serious eye damage/eye irritation Category 2
Carcinogenicity Category 2

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Section 2. Hazards identification

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Xi - Irritant

2.2 Label elements



Signal Word: Warning

Hazard Statements:
H319 - Causes serious eye irritation
H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child

P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash face, hands and any exposed skin thoroughly after handling
P281 - Use personal protective equipment as required
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P337 + P313 - If eye irritation persists: Get medical advice/attention

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Nicotinic Acid 59-67-6	60-80	Present	Xi, R36	Eye Irrit. 2 (H319)	No data available
Hydroxypropyl Methylcellulose 9004-65-3	10-30	NA		Not Hazardous*	No data available
Kollidon 9003-39-8	1-9.9	NA		Not Hazardous*	No data available
Simvastatin 79902-63-9	1-2	NA	Xn, R40 Xn, R62/R63	Carc. 2 (H351) Repr. 2 (H361)	No data available
Titanium Dioxide 13463-67-7	0.1-1	Present		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

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Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Available information support the following: respiratory infection, headaches, abdominal pain, constipation, nausea.

Medical Conditions Aggravated by Exposure: Hypersensitivity to the material and/or similar materials. Pregnancy.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

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6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Nicotinic Acid 59-67-6	1000 mcg/m ³	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Kollidon 9003-39-8	Not Applicable	None
Simvastatin 79902-63-9	20 mcg/m ³ 8-hr TWA	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Nicotinic Acid 59-67-6	3 mg/m ³ for respirable particles and 10 mg/m ³ for inhalable particles				
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				
Kollidon 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	TWA: 10 mg/m ³		4 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Titanium Dioxide 13463-67-7		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	12 mg/m ³ (STEL) 4 mg/m ³ (TWA)

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8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.

Respiratory Protection: Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

Gloves: Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Blue Tablet

Odor: Mild odor.

Odor Threshold: Not determined

pH: Not determined.

Boiling Pt. @ 760 mm Hg (°C): Not determined.

Melting/Freezing Point (°C): Not determined

Flash Point (°C): Not determined.

Evaporation Rate at 20°C: Not determined.

Flammability (Solid): Not determined.

Lower Explosive Limit: Not determined.

Upper Explosive Limit: Not determined.

Vapor Pressure (mm Hg): Not determined.

Vapor Density (Air = 1): Not determined.

Specific Gravity: Not determined.

Solubility(ies): Soluble in: water.

Partition coefficient: n-octanol/water Not determined.

Autoignition Temp. (°C): Not determined.

Decomposition temperature (°C): Not determined.

Viscosity (centipoise): Not determined.

Explosion Severity: Not determined.

Oxidizer Properties: Not determined.

9.2. Other information

Not determined

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Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO_x)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Nicotinic Acid 59-67-6	LD50 =	3720	mg/kg	Mice
		4550		Rabbits
		7000		Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Kollidon 9003-39-8	LD50 =	100000	mg/kg	Rats
		1040		Rabbits
		40000		Mice
Simvastatin 79902-63-9	LD50 =	4438	mg/kg	Rats
	LD50 =	3000		Mice
	LD50 >=	5000		Dogs

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Simvastatin 79902-63-9	LD50 (sc) =	672	mg/kg	Rats	None.
	LD50 (sc) =	1009		Mice	

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Corrosivity: Not determined.
Dermal Irritation: Not determined.
Eye Irritation: A major ingredient is an eye irritant.
Sensitization: Not determined.
Toxicokinetics/Metabolism: Not determined.
Target Organ Effects: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Simvastatin 79902-63-9	Eyes	Dogs	180	mg/kg	Oral	14 weeks
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years

Reproductive Effects: Active Ingredient : Animal testing did not show any effects on fetal development In animals adverse reproductive effects include: testicular atrophy.
Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Simvastatin 79902-63-9	Dogs	10	mg/kg	Oral	3 months

Carcinogenicity: Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Simvastatin 79902-63-9	Liver	Rats Mice	50 100	Oral	mg/kg	2 years 18 months
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Simvastatin 79902-63-9	Negative	Negative	No Data.	Negative

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Nicotinic Acid 59-67-6	60-80	520	Oncorhynchus mykiss	96 Hours

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Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Nicotinic Acid 59-67-6	60-80	77	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Nicotinic Acid 59-67-6	60-80	90	Desmodesmus subspicatus	72 Hours

12.2. Persistence and degradability

Data for component (s) given below.

Chemical Name	Percent	% Degradation	Duration
Nicotinic Acid 59-67-6	60-80	100	Unspecified

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

- 1. EC50:** Concentration in water that produces 50% mortality in *Daphnia* sp.
- 2. LC50:** Concentration in water that produces 50% mortality in fish.
- 3. EbC50/ErC50:** Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- 14.1. UN Number:** Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable

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14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Nicotinic Acid 59-67-6	Present	X	X	Not listed.	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Kollidon 9003-39-8	-	X	X	Not listed.	X
Simvastatin 79902-63-9	-	-	-	Not listed.	-
Titanium Dioxide 13463-67-7	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Nicotinic Acid 59-67-6	Present	-	X	X	Present	HSR003773
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	Present	
Kollidon 9003-39-8	Present	-	X	X	Present	
Simvastatin 79902-63-9	-	Present	X	-	-	
Titanium Dioxide 13463-67-7	Present	-	X	X	Present	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Nicotinic Acid	60-80	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	10-30	Not Listed	Not Listed	Not Listed
Kollidon	1-9.9	Not Listed	Not Listed	Not Listed
Simvastatin	1-2	Not Listed	Not Listed	Not Listed
Titanium Dioxide	0.1-1	Not Listed	Not Listed	Not Listed

SARA 313 Information

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Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Nicotinic Acid	60-80	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	10-30	No	Not Applicable	Not applicable
Kollidon	1-9.9	No	Not Applicable	Not applicable
Simvastatin	1-2	No	Not Applicable	Not applicable
Titanium Dioxide	0.1-1	No	Not Applicable	Not applicable

Immediate Health: Yes
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:
Health: 1
Fire: 1
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Full text of H-Statements referred to under sections 2 and 3

H319 - Causes serious eye irritation, H351 - Suspected of causing cancer if inhaled, H361 - Suspected of damaging fertility or the unborn child if inhaled

Document Authored By: Occupational and Environmental Toxicology

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Supersedes the SDS dated: Feb-08-2008

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