

Simvastatin Formulation

Version 6.0	Revision Date: 23.03.2020	SDS Nu 24353-0		Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
SECTION	N 1. PRODUCT AND C	OMPANY II	DENTIFICA	TION
Product name		: Sim	vastatin For	mulation
Man	ufacturer or supplier	s details		
Com	npany	: Org	anon & Co.	
Add	ress		a Treze de N npinas, São	laio, 1161 Paulo, Brazil B-2220
Tele	phone	: 551	-430-6000	
Eme	ergency telephone	: 215	-631-6999	
E-m	ail address	: EHS	SSTEWARD	@organon.com
	ommended use of the		and restrict	

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

	Skin irritation	:	Category 3
	Skin sensitization	:	Category 1
I	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 in accordance with ABNT NBR 14725 Standard

Hazard pictograms		
Signal Word	: Warning	
Hazard Statements	 H316 Causes mild skin irritation. H317 May cause an allergic skin reaction. H373 May cause damage to organs (Liver, muscle, optic needs) Hyperbolic through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects. 	erve,



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Preca	autionary Statements	P280 Wear p Response: P314 Get me P333 + P313 vice/ attentior	elease to the environment. rotective gloves. dical advice/ attention if you feel unwell. If skin irritation or rash occurs: Get medical ad-

Other hazards which do not result in classification

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Simvastatin	79902-63-9	Skin irritation, Category 2 Skin sensitization, Category 1 Specific target organ toxicity - repeated exposure (Liver, mus- cle, optic nerve, Eye), Category 1 Short-term (acute) aquatic hazard, Category 2 Long-term (chronic) aquatic hazard, Category 2	>= 5 -< 10
Starch	9005-25-8		>= 5 -< 10
Cellulose	9004-34-6		>= 1 -< 5
Citric acid monohydrate	5949-29-1	Eye irritation, Category 2A	>= 1 -< 5
Titanium dioxide	13463-67-7	Carcinogenicity (Inha- lation), Category 2	>= 0,1 -< 1

SECTION 4. FIRST AID MEASURES

General advice

: In the case of accident or if you feel unwell, seek medical advice immediately.

When symptoms persist or in all cases of doubt seek medical advice.



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lf inha	aled	•	: If inhaled, remove to fresh air. Get medical attention.					
In case of skin contact		:	In case of contac Remove contami Get medical atter Wash clothing be	t, immediately flush skin with plenty of water. nated clothing and shoes. ntion.				
In ca	se of eye contact	:	If in eyes, rinse w					
lf swa	If swallowed		If swallowed, DO Get medical atter	NOT induce vomiting. ntion if symptoms occur. oughly with water.				
	important symptoms effects, both acute and red	:	 Causes mild skin irritation. May cause an allergic skin reaction. May cause damage to organs through prolonged or rep exposure. Dust contact with the eyes can lead to mechanical irrita 					
Prote	Protection of first-aiders Notes to physician		First Aid respond and use the record	ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).				
Notes				ically and supportively.				
SECTION	5. FIRE-FIGHTING ME	ASL	JRES					
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical					
	Unsuitable extinguishing media		None known.					
Spec fightir	ific hazards during fire ng	:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health.				
Haza ucts	rdous combustion prod-	:	Carbon oxides					
Spec ods	Specific extinguishing meth- ods			g measures that are appropriate to local cir- the surrounding environment.				

Use water spr	ay to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do
S0.
Evacuate area.

Special protective equipment:In the event of fire, wear self-contained breathing apparatus.for fire-fightersUse personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided.



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Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.	
 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 surfawith compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they 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 employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regacertain local or national requirements. 	aces / are items

SECTION 7. HANDLING AND STORAGE

Technical measures :	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation : Advice on safe handling :	Use only with adequate ventilation. 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.
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.
Conditions for safe storage :	
Materials to avoid :	Do not store with the following product types: Strong oxidizing agents Organic peroxides



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Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis	
Simvastatin	79902-63-9	TWA	25 µg/m3 (OEB 3)	Internal	
	Further information: DSEN				
		Wipe limit	250 µg/100 cm ²	Internal	
Starch	9005-25-8	TWA	10 mg/m³	ACGIH	
Cellulose	9004-34-6	TWA	10 mg/m³	ACGIH	
Titanium dioxide	13463-67-7	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 : Filter type : Hand protection :	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type
Material :	Chemical-resistant gloves
Remarks : Eye protection :	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection :	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

: powder



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	Color		:	No data available	9
	Odor		:	odorless	
	Odor Threshold		:	No data available)
	рН		:	No data available)
	Melting	point/freezing point	:	No data available	9
	Initial b range	oiling point and boiling	:	No data available	
	Flash p	oint	:	Not applicable	
	Evapor	ation rate	:	Not applicable	
	Flamma	ability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.
	Flamma	ability (liquids)	:	No data available	
	Upper explosion limit / Upper flammability limit		:	No data available	
	Lower explosion limit / Lower flammability limit		:	No data available	
	Vapor p	pressure	:	Not applicable	
	Relative	e vapor density	:	Not applicable	
	Relative	e density	:	No data available	
	Density		:	No data available	
	Solubili Wat	ty(ies) er solubility	:	No data available	9
	Partition octanol	n coefficient: n-	:	Not applicable	
		hition temperature	:	No data available	9
	Decom	position temperature	:	No data available	
	Viscosi [.] Visc	ty osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Particle	size	:	No data available	



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SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	 Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. 	
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.	
Incompatible materials	: Oxidizing agents	
Hazardous decomposition products	: No hazardous decomposition products are known.	

SECTION 11. TOXICOLOGICAL INFORMATION

:	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



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Titan	ium dioxide:				
Acute	e oral toxicity	:	LD50 (Rat): > 5.000 mg/kg		
Acute	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 inhala- tion toxicity		
Skin	corrosion/irritation				
Caus	es mild skin irritation.				
Com	ponents:				
Simv	astatin:				
Spec Rema		:	Rabbit Moderate skin irri	tation	
Citric	c acid monohydrate:				
Spec Resu	ies	:	Rabbit No skin irritation		
Titan	ium dioxide:				
Spec Resu	ies	:	Rabbit No skin irritation		
Serio	ous eye damage/eye irı	ritati	ion		
	lassified based on availa				
	ponents:				
	astatin:				
Spec Rema	ies arks	:	Rabbit slight irritation		
Starc	:h:				
Spec Resu	ies It	:	Rabbit No eye irritation		
Citric	acid monohydrate:				
Spec Resu		:	Rabbit Irritation to eyes,	reversing within 21 days	
Titan	ium dioxide:				
Spec Resu	ies	:	Rabbit No eye irritation		



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Resp	iratory or skin sensit	izatio	n	
Skin	sensitization			
May	cause an allergic skin i	eactic	n.	
Resp	iratory sensitization			
	lassified based on ava	ilable	information.	
	ponents:			
Simv	astatin:			
	ssment	:	Probability or ev	idence of skin sensitization in humans
Resu		:	positive	
Starc	:h:			
Test		:	Maximization Te	est
	es of exposure	:	Skin contact	
Spec Resu			Guinea pig negative	
			- 3	
	ium dioxide:			
Test	Type es of exposure	:	Local lymph noc Skin contact	le assay (LLNA)
Spec		:	Mouse	
Resu		÷	negative	
	n cell mutagenicity lassified based on ava	ilable	information.	
	ponents:			
Simv	astatin:		Test Type: Bact	erial reverse mutation assay (AMES)
Simv		:	Test Type: Bact Result: negative	erial reverse mutation assay (AMES)
Simv	astatin:	:	Result: negative	ine elution assay
Simv	astatin:	:	Result: negative Test Type: Alkal Result: negative	ine elution assay mosomal aberration
Simv	astatin:	:	Result: negative Test Type: Alkal Result: negative Test Type: Chro Result: negative	ine elution assay mosomal aberration ro mammalian cell gene mutation test
Simv	astatin:	:	Result: negative Test Type: Alkal Result: negative Test Type: Chro Result: negative Test Type: In vit	ine elution assay mosomal aberration ro mammalian cell gene mutation test onucleus test te: Oral

Starch:



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Geno	Genotoxicity in vitro		Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
 Cellu	llose:			
	otoxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
			Test Type: In vitro Result: negative	o mammalian cell gene mutation test
Genc	otoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in viv cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative	
II Citri	c acid monohydrate:			
	ptoxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
			Test Type: in vitro Result: positive	micronucleus test
			Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
Genc	otoxicity in vivo	:		enicity (in vivo mammalian bone-marrow chromosomal analysis) : Ingestion
•• Titan	nium dioxide:			
	otoxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)
Geno	otoxicity in vivo	:	Test Type: In vivo Species: Mouse Result: negative	micronucleus test
	inogenicity			
	classified based on availa	able	information.	
	ponents:			
	vastatin:			
Spec Appli	ies cation Route	:	Mouse Oral	
Expo	sure time	:	< 92 weeks	
	et Organs	:	Harderian gland	
Rema	or Type arks	:	Liver, Lungs The significance of	of these findings for humans is not certain.



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Expos	ation Route sure time r Type	:	Rat Oral 2 Years Liver, Thyroid The significance o	of these findings for humans is not certain.	
	es ation Route sure time	:	Rat Ingestion 72 weeks negative		
Specie Applic	ation Route sure time od t		Rat inhalation (dust/m 2 Years OECD Test Guide positive The mechanism c mans.		
ment	II		Limited evidence of carcinogenicity in inhalation studies with animals.		
	oductive toxicity assified based on availa	able	information.		
Comp	oonents:				
	astatin: s on fertility	:	Test Type: Fertilit Species: Rat, mal Application Route Fertility: LOAEL: 2	e	
Effect	s on fetal development	:	Species: Rat Application Route Embryo-fetal toxic Result: No teratog Test Type: Embry Species: Rabbit Application Route Embryo-fetal toxic Result: No teratog	city.: NOAEL: 25 mg/kg body weight genic effects., No adverse effects. ro-fetal development : Oral city.: NOAEL: 10 mg/kg body weight genic effects., No adverse effects.	
			Species: Rat	ro-fetal development	

Application Route: Oral

Embryo-fetal toxicity.: LOAEL: 60 mg/kg body weight Result: Teratogenic potential.



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			Remarks: Based on data from similar materials
Cellul	050.		
	s on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects	s on fetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
Citric	acid monohydrate:		
	s on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
STOT	-single exposure		
	position bound on availa	blo	information
NOL CI	assified based on availa	Die	
	-repeated exposure	DIE	e mornauon.
STOT	-repeated exposure ause damage to organs		
STOT May c expos	-repeated exposure ause damage to organs		
STOT May c expos <u>Comp</u>	-repeated exposure ause damage to organs ure.		
STOT May c expos <u>Comp</u> Simva	-repeated exposure ause damage to organs ure. ponents:		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye
STOT May c expos Comp Simva Target Asses	-repeated exposure ause damage to organs ure. ponents: astatin: t Organs		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated
STOT May c expos Comp Simva Targe Asses Repea	-repeated exposure ause damage to organs ure. ponents: astatin: t Organs sment		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated
STOT May c expos Comp Simva Targe Asses Repea <u>Comp</u>	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents:		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated
STOT May c expos Comp Simva Targe Asses Repea <u>Comp</u>	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin:		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated
STOT May c expos Comp Simva Asses Repea Comp Simva Specia NOAE	-repeated exposure ause damage to organs ure. oonents: astatin: t Organs sment ated dose toxicity oonents: astatin: es		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated exposure.
STOT May c expos Comp Simva Targe Asses Repea Comp Simva Specie NOAE LOAE	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin: es statin: es		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated exposure. Rat 5 mg/kg 30 mg/kg
STOT May c expos Comp Simva Targe Asses Repea Comp Simva Specie NOAE LOAE Applic	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin: es tL L ation Route	: : : :	iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated exposure. Rat 5 mg/kg 30 mg/kg Oral
STOT May c expos Comp Simva Targe Asses Repea Comp Simva Specie NOAE LOAE Applic Expos	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin: es statin: es	: : : :	iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated exposure. Rat 5 mg/kg 30 mg/kg
STOT May c expos Comp Simva Targe Asses Repea Comp Simva Specie NOAE LOAE Applic Expos Targe	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin: es L L ation Route cure time t Organs	: : : :	iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated exposure. Rat 5 mg/kg 30 mg/kg Oral 14 - 104 Weeks
STOT May c expos Comp Simva Target Asses Repea Simva Specia NOAE LOAE Applic Expos Target	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin: es iL L ation Route oure time t Organs es L		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeater exposure. Rat 5 mg/kg 30 mg/kg Oral 14 - 104 Weeks Liver, Testis, Musculo-skeletal system, Eye Dog 10 mg/kg
STOT May c expos Comp Simva Targe Asses Repea Comp Simva Specia NOAE LOAE Applic Expos Targe	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin: es iL L ation Route oure time t Organs es L ation Route		 iver, muscle, optic nerve, Eye) through prolonged or repeate Causes damage to organs through prolonged or repeate exposure. Rat 5 mg/kg 30 mg/kg Oral 14 - 104 Weeks Liver, Testis, Musculo-skeletal system, Eye Dog 10 mg/kg Oral
STOT May c expos Comp Simva Targei Asses Repea Comp Simva Specie NOAE LOAE Applic Expos Targei	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin: es iL L ation Route oure time t Organs es L		iver, muscle, optic nerve, Eye) through prolonged or repeat Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated exposure. Rat 5 mg/kg 30 mg/kg Oral 14 - 104 Weeks Liver, Testis, Musculo-skeletal system, Eye Dog 10 mg/kg
STOT May c expos Comp Simva Targei Asses Repea Comp Simva Specie NOAE LOAE Applic Expos Targei	-repeated exposure ause damage to organs ure. conents: astatin: t Organs sment ated dose toxicity conents: astatin: es statin: es L ation Route oure time t Organs es L ation Route oure time t Organs		 iver, muscle, optic nerve, Eye) through prolonged or repeated Liver, muscle, optic nerve, Eye Causes damage to organs through prolonged or repeated exposure. Rat 5 mg/kg 30 mg/kg Oral 14 - 104 Weeks Liver, Testis, Musculo-skeletal system, Eye Dog 10 mg/kg Oral 14 - 104 Weeks



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	L cation Route t Organs	: 50 mg/kg : Oral : Liver, Kidney		
	es EL cation Route sure time	: Rat : >= 2.000 mg/k : Skin contact : 28 Days : OECD Test Gu	-	
	es	: Rat : >= 9.000 mg/k : Ingestion : 90 Days	g	
Specie NOAE LOAE Applic	EL	: Rat : 4.000 mg/kg : 8.000 mg/kg : Ingestion : 10 Days		
Specie NOAE Applic Expos	EL cation Route sure time	: Rat : 24.000 mg/kg : Ingestion : 28 Days		
Specie NOAE Applic Expos	es EL cation Route sure time	: Rat : 10 mg/m ³ : inhalation (dus : 2 y	t/mist/fume)	
Not cl	ation toxicity assified based on ava rience with human e			
-	oonents:			
	astatin: contact tion	: Target Organs Symptoms: up dominal pain, o	produce an allergic reaction. : Liver per respiratory tract infection, Headache, Ab- constipation, Nausea : Musculo-skeletal system	



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ECTION	CTION 12. ECOLOGICAL INFORMATION					
Ecoto	oxicity					
Comp	oonents:					
Simva	astatin:					
Toxici	ty to fish	:	LC50 (Pimephales Exposure time: 96 Method: OECD Te			
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te			
Toxici plants	ty to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 96	chneriella subcapitata (green algae)): > 25 6 h		
			NOEC (Pseudokir mg/l Exposure time: 96	chneriella subcapitata (green algae)): 25 Sh		
Toxici	ty to microorganisms	:	EC50: > 30 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition		
			NOEC: 21 mg/l Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition		
Cellul	ose:					
Toxici	ty to fish	:	Exposure time: 48	pes (Japanese medaka)): > 100 mg/l s h on data from similar materials		
Citric	acid monohydrate:					
	ty to fish	:	LC50 (Pimephales Exposure time: 96	s promelas (fathead minnow)): > 100 mg/l 5 h		
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 24	agna (Water flea)): 1.535 mg/l ⊦h		
Titani	um dioxide:					
	ty to fish	:	LC50 (Oncorhync Exposure time: 96 Method: OECD Te			
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): > 100 mg/l s h		



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Toxicity	/ to microorganisms	:	EC50: > 1.000 m Exposure time: 3 Method: OECD T	
Persist	tence and degradabi	lity		
Compo	onents:			
Simva	statin:			
Biodeg	radability	:	Result: rapidly de	gradable
Stability	y in water	:	Hydrolysis: 50 %	(3,2 d)
Celluic	ose:			
Biodeg	radability	:	Result: Readily b	iodegradable.
Citric a	acid monohydrate:			
Biodeg	radability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD T	97 %
Bioaco	umulative potential			
Compo	onents:			
Simva	statin:			
Partitio octanol	n coefficient: n- I/water	:	log Pow: > 4,07	
	acid monohydrate: n coefficient: n- l/water	:	log Pow: -1,72	
	a available			
	adverse effects a available			

SECTION 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.



Simvastatin Formulation

Version 5.0	Revision Date: 23.03.2020	SDS Number: 24353-00015	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
SECTION	14. TRANSPORT IN	FORMATION	
Interi	national Regulations	6	
UNR ⁻ Not re	TDG egulated as a danger	ous good	
	-DGR egulated as a danger	ous good	
	-Code egulated as a danger	ous good	
	sport in bulk accord	-	ARPOL 73/78 and the IBC Code
Dom	estic regulation		
ANT	r egulated as a danger	ous good	
ANT Not re			
ANTT Not re SECTION Safet mixtu	egulated as a danger 15. REGULATORY I y, health and enviro ure	INFORMATION	/legislation specific for the substance or
ANTT Not re SECTION Safet mixtu Natio	egulated as a danger 15. REGULATORY I ty, health and enviro ure nal List of Carcinoger	INFORMATION	
ANTT Not re SECTION Safet mixtu Natio	egulated as a danger 15. REGULATORY I y, health and enviro ure	INFORMATION	
ANTT Not re SECTION Safet mixtu Natio Grou Titani	agulated as a dangero 15. REGULATORY I ty, health and enviro ure nal List of Carcinoger p 2B: Possibly carcino ium dioxide I. List of chemicals co	INFORMATION	s - (LINACH) 13463-67-7
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ANTT Not re SECTION Safet mixtu Natio Group Titani Brazii Police	agulated as a dangero 15. REGULATORY I 17. REGULATORY I 17	INFORMATION	s - (LINACH) 13463-67-7 al : Not applicable in the following inventories:
ANTT Not re SECTION Safet mixtu Natio Grouy Titani Brazil Police Intern The i	agulated as a dangero 15. REGULATORY I 17. REGULATORY I 17	INFORMATION Inmental regulations nic Agents for Humans ogenic to humans Introlled by the Federa	s - (LINACH) 13463-67-7 al : Not applicable in the following inventories: ed

Further information

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Material Safety		eChem Portal search results and European Chemicals Agen-
Data Sheet		cy, 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.



Simvastatin Formulation

Version 6.0	Revision Date: 23.03.2020	SDS Number: 24353-00015	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
Full to ACGI	ext of other abbreviat H		reshold Limit Values (TLV)
ACGI	H / TWA	: 8-hour, time-wei	ghted average
Land Carcin Stand x% re ENCS x% gr tem; 0 - Inte Equip centra cal Si Mariti ganis centra Letha n.o.s. Conce Loadi Zeala ment; lative es; ((1907/ Autho ture; Si tion o tions; - Ver	of Brazil; ASTM - Ame nogen, Mutagen or Re lardisation; DSL - Dome esponse; ELx - Loadin S - Existing and New C rowth rate response; El GLP - Good Laboratory ment of Ships carrying ation; ICAO - Internatio ubstances in China; IM me Organization; ISHL ation for Standardizatio ation to 50 % of a test I Dose); MARPOL - Ir - Not Otherwise Speci entration; NO(A)EL - N ng Rate; NOM - Officia nd Inventory of Chemic OPPTS - Office of Che and Toxic substance; I Q)SAR - (Quantitative 2006 of the European F prisation and Restriction SDS - Safety Data She f Dangerous Goods; TS UNRTDG - United Nat	rican Society for the eproductive Toxicant; estic Substances List g rate associated with chemical Substances RG - Emergency Resp Practice; IARC - Inter t Association; IBC - g Dangerous Chemica nal Civil Aviation Orga IDG - International M - Industrial Safety ar on; KECI - Korea Exis population; LD50 - Le thernational Convention fied; Nch - Chilean No o Observed (Adverse al Mexican Norm; NTF cals; OECD - Organiz emical Safety and Poll PICCS - Philippines Ir o) Structure Activity Parliament and of the G on of Chemicals; SAD et; TCSI - Taiwan Che SCA - Toxic Substance ions Recommendation	ces; ANTT - National Agency for Transport by Testing of Materials; bw - Body weight; CMR - DIN - Standard of the German Institute for (Canada); ECx - Concentration associated with h x% response; EmS - Emergency Schedule; (Japan); ErCx - Concentration associated with bonse Guide; GHS - Globally Harmonized Sys- national Agency for Research on Cancer; IATA International Code for the Construction and ils in Bulk; IC50 - Half maximal inhibitory con- anization; IECSC - Inventory of Existing Chemi- aritime Dangerous Goods; IMO - International of Health Law (Japan); ISO - International Or- sting Chemicals Inventory; LC50 - Lethal Con- thal Dose to 50% of a test population (Median on for the Prevention of Pollution from Ships; prm; NO(A)EC - No Observed (Adverse) Effect P - National Toxicology Program; NZIoC - New ation for Economic Co-operation and Develop- ution Prevention; PBT - Persistent, Bioaccumu- wentory of Chemicals and Chemical Substanc- Relationship; REACH - Regulation (EC) No Council concerning the Registration, Evaluation, T - Self-Accelerating Decomposition Tempera- emical Substance Inventory; TDG - Transporta- es control Act (United States); UN - United Na- hs on the Transport of Dangerous Goods; vPvB HMIS - Workplace Hazardous Materials Infor-

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.

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