

Simvastatin Formulation

Versio 5.3	on	Revision Date: 23.03.2020		S Number: 345-00015	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
SECT	FION 1	. PRODUCT AND COI	MPA	NY IDENTIFICAT	ION
F	Produc	t name	:	Simvastatin Forr	nulation
N	Manufa	acturer or supplier's o	deta	ils	
C	Compa	ny	:	Organon & Co.	
A	Addres	S	:	30 Hudson Stree Jersey City, New	et, 33nd floor / Jersey, U.S.A 07302
Т	Teleph	one	:	551-430-6000	
E	Emerge	ency telephone	:	215-631-6999	
E	E-mail	address	:	EHSSTEWARD	@organon.com
F	Recom	mended use of the cl	hem	ical and restriction	
		mended use	:		
SECT	FION 2	. HAZARDS IDENTIFI	САТ	ION	
c	GHS C	lassification			
	Skin irr		:	Category 3	
S	Skin se	ensitization	:	Category 1	
		c target organ toxicity - ed exposure	:	Category 2 (Live	r, muscle, optic nerve, Eye)
	Short-te nazard	erm (acute) aquatic	:	Category 3	
L	_ong-te	erm (chronic) aquatic	:	Category 3	

GHS label elements

Hazard pictograms

hazard



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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 nerve, Eye) through prolonged or repeated exposure.
 H412 Harmful to aquatic life with long lasting effects.



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Preca	uutionary Statements	the workplace P273 Avoid re	inated work clothing should not be allowed out of
		P314 Get me P333 + P313 vice/ attentior	IF ON SKIN: Wash with plenty of water. dical advice/ attention if you feel unwell. If skin irritation or rash occurs: Get medical ad- i. Take off contaminated clothing and wash it before
		Disposal: P501 Dispose disposal plant	e of contents/ container to an approved waste
Othe	r hazards which do no	ot result in classific	ation

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.	Concentration (% w/w)
Simvastatin	79902-63-9	>= 5 -< 10
Starch	9005-25-8	>= 5 -< 10
Cellulose	9004-34-6	>= 1 -< 5
Citric acid monohydrate	5949-29-1	>= 1 -< 5
Titanium dioxide	13463-67-7	>= 0,1 -< 1

SECTION 4. FIRST AID MEASURES

General advice	In the case of accident or if you feel unwell, s advice immediately. When symptoms persist or in all cases of do advice.	
If inhaled	If inhaled, remove to fresh air. Get medical attention.	
In case of skin contact	 In case of contact, immediately flush skin wit Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. 	h plenty of water.
In case of eye contact	If in eyes, rinse well with water. Get medical attention if irritation develops an	d persists.
If swallowed	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur.	



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	important symptoms effects, both acute and red	:	Causes mild s May cause an May cause da exposure.	allergic skin reaction. mage to organs through prolonged or repeated
Prote	ection of first-aiders	:	First Aid respo and use the re	vith the eyes can lead to mechanical irritation. Inders should pay attention to self-protection, accommended personal protective equipment ntial for exposure exists (see section 8).
Note	s to physician	:		natically and supportively.
SECTION	5. FIRE-FIGHTING ME	٩SL	IRES	
Suita	ble extinguishing media	:	Water spray Alcohol-resista Carbon dioxide Dry chemical	
Unsu medi	iitable extinguishing a	:	None known.	
Spec fighti	ific hazards during fire ng	:	concentrations potential dust	ing dust; fine dust dispersed in air in sufficient s, and in the presence of an ignition source is a explosion hazard. ombustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides	i
Spec ods	ific extinguishing meth-	:	cumstances an Use water spra	ning measures that are appropriate to local cir- nd the surrounding environment. ay to cool unopened containers. maged containers from fire area if it is safe to d
	ial protective equipment e-fighters	:	In the event of	fire, wear self-contained breathing apparatus. 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. 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.



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		disposal of thi employed in the determine wh Sections 13 a	nal regulations may apply to releases and s material, as well as those materials and items he cleanup of releases. You will need to ich regulations are applicable. nd 15 of this SDS provide information regarding r national requirements.
SECTION	7. HANDLING AND ST	ORAGE	
Tech	nical measures	causing an ex Provide adequ	ty may accumulate and ignite suspended dust plosion. Jate precautions, such as electrical grounding or inert atmospheres.
	/Total ventilation e on safe handling	 Use only with Do not get on Do not breath Do not swallor Avoid contact Handle in acc practice, base assessment Minimize dust Keep containe Keep away from Take precauti 	adequate ventilation. skin or clothing. e dust. w.
	itions for safe storage rials to avoid	: Keep in prope Store in accor	

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Simvastatin	79902-63-9	TWA	25 µg/m3 (OEB 3)	Internal	
	Further inform	ation: DSEN			
		Wipe limit	250 µg/100 cm ²	Internal	
Starch	9005-25-8	CMP	10 mg/m ³	AR OEL	
	Further inform	ation: A4 - Not c	lassifiable as a huma	n carcinogen,	
	lung, Dermatiti	S			
		TWA	10 mg/m ³	ACGIH	
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL	
	Further inform	Further information: Irritation			
		TWA	10 mg/m ³	ACGIH	
Titanium dioxide	13463-67-7	CMP	10 mg/m ³	AR OEL	



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		Further in	ther information: A4 - Not classifiable as a human carcinoge				
			TWA	10 mg/m ³ (Titanium dioxide)	ACGIH		
Engir	neering measures	design ar protect p Containm are requi the comp containm	nd operated in ac roducts, workers nent technologies red to control at s	nould be implemented be cordance with GMP pri , and the environment. s suitable for controlling source and to prevent n olled areas (e.g., open-f	nciples to compounds nigration of		
Perso	onal protective equip	ment					
Respi	iratory protection	exposure	assessment der	ventilation is not availat nonstrates exposures c use respiratory protect	utside the		
	ter type protection	: Particulat					
Ма	aterial	: Chemica	l-resistant gloves				
	emarks rotection	: Wear saf If the wor mists or a Wear a fa	k environment of aerosols, wear th aceshield or othe for direct contact	side shields or goggles. r activity involves dusty e appropriate goggles. r full face protection if th to the face with dusts,	conditions, nere is a		
Skin a	and body protection	: Work uni Additiona task bein disposab Use appr	form or laborator Il body garments g performed (e.g le suits) to avoid	y coat. should be used based ., sleevelets, apron, gau exposed skin surfaces. ng techniques to remove	untlets,		
Hygie	ne measures	: If exposu eye flush working p When us Wash cou The effec engineeri appropria industrial	re to chemical is ing systems and blace. ing do not eat, dr ntaminated clothi tive operation of ing controls, prop ate degowning ar	ing before re-use. a facility should include per personal protective end decontamination prot ing, medical surveillance	e review of equipment, cedures,		

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	odorless

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Odo	Threshold	:	No data available	9
pН		:	No data available	9
Melti	ng point/freezing point	:	No data available	9
Initia rang	l boiling point and boiling e	:	No data available	9
Flasl	n point	:	Not applicable	
Evap	poration rate	:	Not applicable	
Flam	imability (solid, gas)	:	May form explosi handling or other	ive dust-air mixture during processing, means.
Flam	mability (liquids)	:	No data available	9
	er explosion limit / Upper mability limit	:	No data available	9
	er explosion limit / Lower mability limit	:	No data available	9
Vapo	or pressure	:	Not applicable	
Rela	tive vapor density	:	Not applicable	
Rela	tive density	:	No data available	9
Dens	sity	:	No data available	9
	bility(ies) /ater solubility	:	No data available	9
	tion coefficient: n-	:	Not applicable	
	nol/water ignition temperature	:	No data available	9
Deco	omposition temperature	:	No data available	9
Visco V	osity iscosity, kinematic	:	Not applicable	
Expl	osive properties	:	Not explosive	
Oxid	izing properties	:	The substance o	r mixture is not classified as oxidizing.
Parti	cle size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY

Reactivity

: Not classified as a reactivity hazard.



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	cal stability ility of hazardous reac-	:	handling or other	ve dust-air mixture during processing,			
Incomp	ons to avoid patible materials lous decomposition ts	:	 Heat, flames and sparks. Avoid dust formation. Oxidizing agents No hazardous decomposition products are known. 				
SECTION 1	1. TOXICOLOGICAL I	NFC	RMATION				
Informa exposu	ation on likely routes of Ire	:	Inhalation Skin contact Ingestion Eye contact				
	toxicity ssified based on availa	ble i	information.				
Comp	onents:						
Simva Acute o	statin: oral toxicity	:	LD50 (Rat): 5.000	mg/kg			
			LD50 (Mouse): 3.8	300 mg/kg			
Starch							
	oral toxicity	:	LD50 (Rat): > 5.00	00 mg/kg			
Acute	dermal toxicity	:	LD50 (Rabbit): > 2	2.000 mg/kg			
Celluio	ose:						
Acute	oral toxicity	:	LD50 (Rat): > 5.00	00 mg/kg			
Acute i	nhalation toxicity	:	LC50 (Rat): > 5,8 Exposure time: 4 I Test atmosphere:	n			
Acute	dermal toxicity	:	LD50 (Rabbit): > 2	2.000 mg/kg			
	acid monohydrate: oral toxicity	:	LD50 (Mouse): 5.4	400 mg/kg			
Acute	dermal toxicity	:	LD50 (Rat): > 2.00 Method: OECD Te Assessment: The toxicity				





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Acute inhalation toxicity		:	LC50 (Rat): > 6 Exposure time: Test atmospher Assessment: Th tion toxicity	4 h
-	corrosion/irritation es mild skin irritation.			
<u>Comp</u>	oonents:			
Simva	astatin:			
Speci Rema		:	Rabbit Moderate skin i	ritation
Citric	acid monohydrate:			
Speci Resul		:	Rabbit No skin irritatior)
Titani	ium dioxide:			
Speci Resul		:	Rabbit No skin irritatior	1
	us eye damage/eye ii			
	assified based on avai	lable	information.	
-	oonents:			
	astatin:		Data	
Speci Rema		:	Rabbit slight irritation	
Starc	h:			
Speci Resul		:	Rabbit No eye irritation	
Citric	acid monohydrate:			
Citric Speci Resul		:	Rabbit Irritation to eyes	, reversing within 21 days
Speci Resul	es	:		s, reversing within 21 days
Speci Resul	es t ium dioxide: es	:		
Speci Resul Titani Speci Resul	es t ium dioxide: es	: : :	Irritation to eyes Rabbit No eye irritation	

May cause an allergic skin reaction.



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Respiratory sensitization		
Not classified based on ava	ailable information.	
Components:		
Simvastatin:		
Assessment Result	: Probability or ev : positive	idence of skin sensitization in humans
Starch:		
Test Type	: Maximization Te	est
Routes of exposure Species	: Skin contact : Guinea pig	
Result	: negative	
Titanium dioxide:		
Test Type Routes of exposure	: Local lymph noo : Skin contact	le assay (LLNA)
Species	: Mouse	
Result	: negative	
Components:	ailable information.	
		erial reverse mutation assay (AMES)
<u>Components:</u> Simvastatin:	: Test Type: Bact Result: negative	ine elution assay
<u>Components:</u> Simvastatin:	: Test Type: Bact Result: negative Test Type: Alka Result: negative	ine elution assay mosomal aberration
<u>Components:</u> Simvastatin:	: Test Type: Bact Result: negative Test Type: Alka Result: negative Test Type: Chro Result: negative	ine elution assay mosomal aberration ro mammalian cell gene mutation test
<u>Components:</u> Simvastatin:	 Test Type: Bact Result: negative Test Type: Alka Result: negative Test Type: Chro Result: negative Test Type: In vit Result: negative Test Type: In vit Result: negative 	ine elution assay mosomal aberration ro mammalian cell gene mutation test onucleus test
<u>Components:</u> Simvastatin: Genotoxicity in vitro	: Test Type: Bact Result: negative Test Type: Alka Result: negative Test Type: Chro Result: negative Test Type: In vit Result: negative	ine elution assay mosomal aberration ro mammalian cell gene mutation test onucleus test te: Oral
<u>Components:</u> Simvastatin: Genotoxicity in vitro	 Test Type: Bact Result: negative Test Type: Alka Result: negative Test Type: Chro Result: negative Test Type: In vit Result: negative Test Type: In vit Result: negative Test Type: Micro Species: Mouse Application Rou Result: negative 	ine elution assay mosomal aberration ro mammalian cell gene mutation test onucleus test te: Oral
Components: Simvastatin: Genotoxicity in vitro Genotoxicity in vivo Germ cell mutagenicity -	 Test Type: Bact Result: negative Test Type: Alka Result: negative Test Type: Chro Result: negative Test Type: In vit Result: negative Test Type: Micro Species: Mouse Application Rou Result: negative Weight of evided cell mutagen. 	ine elution assay mosomal aberration ro mammalian cell gene mutation test onucleus test te: Oral nce does not support classification as a ge
Components: Simvastatin: Genotoxicity in vitro Genotoxicity in vivo Germ cell mutagenicity - Assessment	 Test Type: Bact Result: negative Test Type: Alka Result: negative Test Type: Chro Result: negative Test Type: In vit Result: negative Test Type: Micro Species: Mouse Application Rou Result: negative Weight of evided cell mutagen. 	ine elution assay mosomal aberration ro mammalian cell gene mutation test onucleus test te: Oral nce does not support classification as a ge



Versior 5.3	n	Revision Date: 23.03.2020		OS Number: 345-00015	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
G	enoto	xicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
				Test Type: In vitro Result: negative	o mammalian cell gene mutation test
G	enoto	xicity in vivo	:	Test Type: Mamn cytogenetic assay Species: Mouse Application Route Result: negative	
Ci	itric a	cid monohydrate:			
		xicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
				Test Type: in vitro Result: positive	o micronucleus test
				Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
G	enoto	xicity in vivo	:		enicity (in vivo mammalian bone-marrow chromosomal analysis) :: Ingestion
Ti	itaniu	m dioxide:			
		xicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
G	enoto	xicity in vivo	:	Test Type: In vivo Species: Mouse Result: negative	o micronucleus test
Ca	arcino	ogenicity			
		ssified based on availa	able	information.	
<u>Co</u>	ompo	onents:			
Si	imvas	statin:			
Ar E> Ta Tu	xposu	tion Route re time Organs Type	:	Mouse Oral < 92 weeks Harderian gland Liver, Lungs The significance of	of these findings for humans is not certain.
Ar Ex		tion Route re time	: : :	Rat Oral 2 Years Liver, Thyroid	



3	Revision Date: 23.03.2020		S Number: 345-00015	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
Rema	rks	:	The significand	e of these findings for humans is not certain.
Cellul	ose:			
Specie	29		Rat	
	ation Route	:	Ingestion	
	sure time	:	72 weeks	
Result		:	negative	
Titani	um dioxide:			
Specie	25		Rat	
•	ation Route	:	inhalation (dus	t/mist/fume)
	sure time	:	2 Years	
Metho		:	OECD Test Gu	ideline 153
Result		:	positive	
Rema		:		n or mode of action may not be relevant in hu
Reina	1K5	·	mans.	n of mode of action may not be relevant in no
Carcir ment	nogenicity - Assess-	:	Limited eviden animals.	ce of carcinogenicity in inhalation studies with
	oonents: astatin:			
Simva	astatin:	:	Test Type: Fer	tility
Simva		:	Test Type: Fer Species: Rat, r	
Simva	astatin:	:	Test Type: Fer Species: Rat, r Application Ro	nale
Simva	astatin:	:	Species: Rat, r Application Ro	nale
Simva Effects	astatin:	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em	nale ute: Oral
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects.
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development it
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development it ute: Oral
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro Embryo-fetal to	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development it
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro Embryo-fetal to Result: No tera Test Type: Em	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development it ute: Oral oxicity.: NOAEL: 10 mg/kg body weight
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rat	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development it ute: Oral oxicity.: NOAEL: 10 mg/kg body weight togenic effects., No adverse effects.
Simva Effects	astatin: s on fertility	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rat Application Ro	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development it ute: Oral oxicity.: NOAEL: 10 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development ute: Oral
Simva Effects	astatin: s on fertility	: :	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rat Application Ro Embryo-fetal to	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development it ute: Oral oxicity.: NOAEL: 10 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development ute: Oral oxicity.: LOAEL: 60 mg/kg body weight
Simva Effects	astatin: s on fertility	: :	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: Teratog	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral oxicity.: NOAEL: 25 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development it ute: Oral oxicity.: NOAEL: 10 mg/kg body weight togenic effects., No adverse effects. bryo-fetal development ute: Oral oxicity.: LOAEL: 60 mg/kg body weight
Simva Effects	astatin: s on fertility s on fetal development	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: Teratog	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral exicity.: NOAEL: 25 mg/kg body weight itogenic effects., No adverse effects. bryo-fetal development it ute: Oral exicity.: NOAEL: 10 mg/kg body weight itogenic effects., No adverse effects. bryo-fetal development ute: Oral exicity.: LOAEL: 60 mg/kg body weight genic potential.
Simva Effects Effects	astatin: s on fertility s on fetal development	:	Species: Rat, r Application Ro Fertility: LOAE Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rabb Application Ro Embryo-fetal to Result: No tera Test Type: Em Species: Rat Application Ro Embryo-fetal to Result: Teratog Remarks: Base	nale ute: Oral L: 25 mg/kg body weight bryo-fetal development ute: Oral exicity.: NOAEL: 25 mg/kg body weight itogenic effects., No adverse effects. bryo-fetal development it ute: Oral exicity.: NOAEL: 10 mg/kg body weight itogenic effects., No adverse effects. bryo-fetal development ute: Oral exicity.: LOAEL: 60 mg/kg body weight genic potential.



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				Species: Rat Application Route Result: negative	: Ingestion
	Effects	on fetal development	:	Test Type: Fertility Species: Rat Application Route Result: negative	y/early embryonic development : Ingestion
	Citric a	cid monohydrate:			
		on fetal development	:	Test Type: Embry Species: Rat Application Route Result: negative	o-fetal development : Ingestion
		single exposure ssified based on availa	ıble	information.	
	STOT-r	epeated exposure			
	May ca exposu		i (Liv	/er, muscle, optic n	erve, Eye) through prolonged or repeated
	<u>Compo</u>	onents:			
	Simvas	statin:			
	Target (Assess		:	Liver, muscle, opt Causes damage t exposure.	ic nerve, Eye o organs through prolonged or repeated
	Repeat	ed dose toxicity			
	Compo	onents:			
	Simvas	statin:			
	Species NOAEL LOAEL	s - tion Route re time	:	Rat 5 mg/kg 30 mg/kg Oral 14 - 104 Weeks Liver, Testis, Mus	culo-skeletal system, Eye
	Exposu Target (tion Route re time Organs	:	Dog 10 mg/kg Oral 14 - 104 Weeks Liver, Testis, Eye	
	Species NOAEL LOAEL Applica Target	tion Route		Rabbit 30 mg/kg 50 mg/kg Oral Liver, Kidney	



rsion B	Revision Date: 23.03.2020	SDS Number: 24345-00015	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
	es EL cation Route sure time	: Rat : >= 2.000 mg/k : Skin contact : 28 Days : OECD Test Ge	-
	es	: Rat : >= 9.000 mg/k : Ingestion : 90 Days	g
Speci NOAE LOAE Applic	ΞL	: Rat : 4.000 mg/kg : 8.000 mg/kg : Ingestion : 10 Days	
Speci NOAE Applic		: Rat : 24.000 mg/kg : Ingestion : 28 Days	
		: Rat : 10 mg/m³ : inhalation (dus : 2 y	:t/mist/fume)
•	ration toxicity lassified based on av	ailable information.	
Ехре	rience with human e	exposure	
<u>Com</u>	oonents:		
	astatin: contact tion	: Target Organs Symptoms: up dominal pain,	produce an allergic reaction. : Liver per respiratory tract infection, Headache, Ab- constipation, Nausea

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Simvastatin:

Target Organs: Musculo-skeletal system



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 NOEC (Pseudokirchneriella subcapitata (green algae)): 25 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 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: : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Toxicity to fish : LC50 (Optyrias latipes (Japanese medaka)): > 100 mg/l Exposure time: 96 h Toxicity to fish : LC50 (Optyrias latipes (Japanese medaka)): > 100 mg/l Exposure time: 96 h Toxicity to fish : LC50 (Optyrias latipes (Japanese medaka)): > 100 mg/l Exposure time: 96 h Toxicity to fish : <th>ersion .3</th> <th>Revision Date: 23.03.2020</th> <th></th> <th>9S Number: 345-00015</th> <th>Date of last issue: 13.09.2019 Date of first issue: 21.10.2014</th>	ersion .3	Revision Date: 23.03.2020		9S Number: 345-00015	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014	
aquatic invertebrates Exposure time: 48 fi 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 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 : EC50 (Daphnia magna (Water flea)): 1.535 mg/l Exposure time: 24 h Titanium dioxide: Toxicity to fish :	Toxicity to fish		Exposure time:		96 h	
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			:			
		y to algae/aquatic	:			
Toxicity to microorganisms : EC50: > 1.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209	Toxicit	y to microorganisms	:	Exposure time: 3	h	



/ersion 5.3	Revision Date: 23.03.2020	SDS Number: 24345-00015	Date of last issue: 13.09.2019 Date of first issue: 21.10.2014
Persi	stence and degradat	bility	
Com	ponents:		
-	astatin: gradability	: Result: rapi	dly degradable
Stabil	lity in water	: Hydrolysis:	50 %(3,2 d)
Cellu			
Biode	egradability	: Result: Rea	adily biodegradable.
	acid monohydrate: egradability	Biodegrada Exposure ti	
Bioad	ccumulative potentia	I	
<u>Com</u>	ponents:		
Partit	astatin: ion coefficient: n- ol/water	: log Pow: >	4,07
Partit	acid monohydrate: ion coefficient: n- ol/water	: log Pow: -1	,72
	lity in soil ata available		
	r adverse effects ata available		

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good



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	G-Code egulated as a dangero	ous good	

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

Not applicable for product as supplied.

SECTION 15. REGULATORY INFORMATION

Safety, health and enviro mixture	onmental regulations/legis	slation specific for the substance or				
Argentina. Carcinogenic Substances and Agents : Not applicable Registry.						
Control of precursors and essential chemicals for the : Not applicable preparation of drugs.						
International Regulations						
International Regulation	S					
-	s roduct are reported in the	following inventories:				
-		following inventories:				
The ingredients of this p	roduct are reported in the	following inventories:				

SECTION 16. OTHER INFORMATION

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/

Full text of other abbreviations

ACGIH AR OEL	USA. ACGIH Threshold Limit Values (TLV) Argentina. Occupational Exposure Limits
ACGIH / TWA AR OEL / CMP	8-hour, time-weighted average TLV (Threshold Limit Value)

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 Chemi-



Simvastatin Formulation

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cal 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 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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