

according to GB/T 16483 and GB/T 17519

# **Simvastatin Formulation**

Vers 4.6	ion	Revision Date: 2020/03/23		S Number: 60-00015	Date of last issue: 2019/09/13 Date of first issue: 2014/10/21
1. P	1. PRODUCT AND COMPANY IDENTIFICATION				
	Product	name	:	Simvastatin Form	ulation
	<b>Manufa</b> Compa	<b>acturer or supplier's d</b> ny	letai :	<b>ls</b> Organon & Co.	
	Address		:	30 Hudson Street Jersey City, New	t, 33nd floor Jersey, U.S.A 07302
	Telepho	one	:	551-430-6000	
	Emerge	ency telephone number	:	215-631-6999	
E-mail address		:	EHSSTEWARD@	lorganon.com	
	Recom	mended use of the ch	omi	cal and restrictio	

#### Recommended use of the chemical and restrictions on use ical

Recommended use	:	Pharmaceution
	•	Filamaceuti

#### 2. HAZARDS IDENTIFICATION

#### **Emergency Overview**

Appearance	: powder			
Colour	: No data available			
Odour	: odourless			
Causes mild skin irritation. May cause an allergic skin reaction. May cause damage to organs				

through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.

#### **GHS Classification**

Skin corrosion/irritation	:	Category 3
Skin sensitisation	:	Category 1
Specific target organ toxicity - repeated exposure	:	Category 2
Short-term (acute) aquatic hazard	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 3
GHS label elements Hazard pictograms	:	



Signal word

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Hazard statements		H373 May cau peated exposu	se an allergic skin reaction. se damage to organs through prolonged or re-
Precautionary statements		the workplace. P273 Avoid re	nated work clothing should not be allowed out of
		P314 Get med P333 + P313 I vice/ attention.	F ON SKIN: Wash with plenty of water. ical advice/ attention if you feel unwell. f skin irritation or rash occurs: Get medical ad- Take off contaminated clothing and wash it before
		<b>Disposal:</b> P501 Dispose disposal plant.	of contents/ container to an approved waste

#### Physical and chemical hazards

Not classified based on available information.

#### Health hazards

Causes mild skin irritation. May cause an allergic skin reaction. May cause damage to organs through prolonged or repeated exposure.

#### **Environmental hazards**

Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

#### 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.

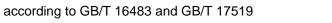
#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Simvastatin	79902-63-9	>= 2.5 -< 10
Starch	9005-25-8	>= 1 -< 10
Cellulose	9004-34-6	>= 1 -< 10
Citric acid monohydrate	5949-29-1	>= 1 -< 10
Titanium dioxide	13463-67-7	>= 0.1 -< 1

#### 4. FIRST AID MEASURES

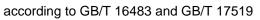




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G	General advice		<ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medica advice.</li> </ul>			
lf	inhaled	:	: If inhaled, remove to fresh air.			
In	In case of skin contact : In case of concernment in case of concernm			ing before reuse.		
In	case of eye contact	:	If in eyes, rinse we			
lf	swallowed	:	If swallowed, DO Get medical attention	tion if irritation develops and persists. NOT induce vomiting. tion if symptoms occur.		
ar	ost important symptoms nd effects, both acute and elayed	:	Causes mild skin May cause an alle May cause damag exposure.	roughly with water. irritation. ergic skin reaction. Ige to organs through prolonged or repeated the eyes can lead to mechanical irritation. ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).		
Pr	rotection of first-aiders	:	First Aid responder and use the recom			
N	Notes to physician			cally and supportively.		
5. FIRE	5. FIREFIGHTING MEASURES					
Su	uitable extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical			
	nsuitable extinguishing edia	:	None known.			
Sp	becific hazards during fire- phting	:	concentrations, ar potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.		
Ha uc	azardous combustion prod- cts	:	Carbon oxides			
Sp	becific extinguishing meth- ds	:	cumstances and t Use water spray to Remove undamag so.	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do		
	pecial protective equipment r firefighters	:	Evacuate area. In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.		

#### 6. ACCIDENTAL RELEASE MEASURES





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	tive equ	al precautions, protec- ipment and emer- procedures	:	Use personal prote Follow safe handli ment recommenda	ng advice and personal protective equip-
	Environmental precautions		:	Prevent further lea Retain and dispos	environment must be avoided. akage or spillage if safe to do so. e of contaminated wash water. hould be advised if significant spillages ed.
		s and materials for ment and cleaning up	:	tainer for disposal. Avoid dispersal of with compressed a Dust deposits sho es, as these may f leased into the atm Local or national r posal of this mater employed in the cl mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

#### 7. HANDLING AND STORAGE

Handling	
Technical measures	<ul> <li>Static electricity may accumulate and ignite suspended dust causing an explosion.</li> <li>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.</li> </ul>
Local/Total ventilation Advice on safe handling	<ul> <li>Use only with adequate ventilation.</li> <li>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.</li> </ul>
Avoidance of contact	: Oxidizing agents
Storage	
Conditions for safe storage	: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents



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Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components 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 inform	ation: DSEN		
		Wipe limit	250 µg/100 cm <sup>2</sup>	Internal
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
Cellulose	9004-34-6	PC-TWA	10 mg/m3	GBZ 2.1- 2007
		TWA	10 mg/m3	ACGIH
Titanium dioxide	13463-67-7	PC-TWA (Total dust)	8 mg/m3	GBZ 2.1- 2007
		TWA	10 mg/m3 (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 con- tainment devices). Minimize open handling.			
Personal protective equipmen	t			
Respiratory protection : Filter type :	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type			
Eye/face 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, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.			
Hand protection	5			
Material :	Chemical-resistant gloves			
Remarks : Hygiene measures :	Consider double gloving. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work-			
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			Wash contaminate The effective oper engineering contro appropriate degov	ot eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, vning and decontamination procedures, monitoring, medical surveillance and the ive controls.
9. PH\	SICAL AND CHEMICAL PR	ROP	ERTIES	
A	ppearance	:	powder	
С	olour	:	No data available	)
0	dour	:	odourless	
0	dour Threshold	:	No data available	)
pl	Н	:	No data available	)
Μ	lelting point/freezing point	:	No data available	
	itial boiling point and boiling ange	:	No data available	3
F	lash point	:	Not applicable	
E	vaporation rate	:	Not applicable	
FI	lammability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
F	lammability (liquids)	:	No data available	
	pper explosion limit / Upper ammability limit	:	No data available	
	ower explosion limit / Lower ammability limit	:	No data available	
V	apour pressure	:	Not applicable	
R	elative vapour density	:	Not applicable	
R	elative density	:	No data available	
D	ensity	:	No data available	
S	olubility(ies) Water solubility	:	No data available	)
	artition coefficient: n- ctanol/water	:	Not applicable	

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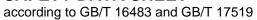


/ersion 1.6	Revision Date: 2020/03/23		S Number: 360-00015	Date of last issue: 2019/09/13 Date of first issue: 2014/10/21			
Auto-	ignition temperature	:	No data available	9			
Deco	Decomposition temperature		: No data available				
	Viscosity Viscosity, kinematic		: Not applicable				
Explo	Explosive properties		Not explosive				
Oxidi	Oxidizing properties		The substance or mixture is not classified as oxidizing.				
Partic	Particle size		: No data available				
0. STABI	ILITY AND REACTIVIT	Y					
	tivity nical stability bility of hazardous reac-		Stable under nor May form explos dling or other me	ive dust-air mixture during processing, han-			
Cond	Conditions to avoid		Heat, flames and Avoid dust forma				
Haza	Incompatible materials Hazardous decomposition products		<ul> <li>Oxidizing agents</li> <li>No hazardous decomposition products are known.</li> </ul>				
1. TOXIC	OLOGICAL INFORMA	TION	I				
Expo	Exposure routes		Inhalation Skin contact Ingestion Eye contact				
	e toxicity lassified based on availa	ahle i	information				
	ponents:						
Simv	astatin:						
Acute	e oral toxicity	:	LD50 (Rat): 5,000	) mg/kg			
			LD50 (Mouse): 3,	800 mg/kg			
Starc							
	e oral toxicity	:	LD50 (Rat): > 5,0				
Acute	e dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg			
Cellu	lose:						
<u>م</u> .							

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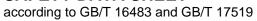


sion	Revision Date: 2020/03/23		S Number: 360-00015	Date of last issue: 2019/09/13 Date of first issue: 2014/10/21			
Acute	inhalation toxicity	:	LC50 (Rat): > Exposure time Test atmosphe	:: 4 h			
Acute	Acute dermal toxicity		: LD50 (Rabbit): > 2,000 mg/kg				
Citric	acid monohydrate:						
Acute	oral toxicity	:	LD50 (Mouse)	: 5,400 mg/kg			
Acute	dermal toxicity	:		2,000 mg/kg D Test Guideline 402 Fhe substance or mixture has no acute dermal			
Titani	um dioxide:						
Acute	oral toxicity	:	LD50 (Rat): >	5,000 mg/kg			
Acute	inhalation toxicity	:	LC50 (Rat): > Exposure time Test atmosphe Assessment: 1 tion toxicity	:: 4 h			
	corrosion/irritation es mild skin irritation.						
Comp	oonents:						
Simva	astatin:						
Specie Rema		:	Rabbit Moderate skin	irritation			
Citric	acid monohydrate:						
Specie Result	es	:	Rabbit No skin irritatio	on			
Titani	um dioxide:						
Specie Result		:	Rabbit No skin irritatio	on			
	u <b>s eye damage/eye i</b> assified based on ava						
<u>Comp</u>	oonents:						
Simva	astatin:						
Specie Rema		:	Rabbit slight irritation				





rsion	Revision Date: 2020/03/23		S Number: 360-00015	Date of last issue: 2019/09/13 Date of first issue: 2014/10/21			
Starc	h:						
Speci	es	:	Rabbit				
Result		:	: No eye irritation				
Citric	acid monohydrate:						
Speci	es	:	Rabbit				
Resul	t	:	Irritation to eye	s, reversing within 21 days			
Titani	um dioxide:						
Speci		:	Rabbit				
Resul	t	:	No eye irritatior	1			
Respi	iratory or skin sens	itisatic	'n				
_	sensitisation						
May c	ause an allergic skin	reaction	on.				
-	iratory sensitisatior assified based on av		information.				
Components:							
Simva	astatin:						
	sment	:	: Probability or evidence of skin sensitisation in humans				
Resul	t	:	positive				
Starc	h:						
Test T	Гуре	:	Maximisation T	est			
	sure routes	:	Skin contact				
Speci		:	: Guinea pig				
Resul	t	:	negative				
	um dioxide:						
Test T		:		de assay (LLNA)			
	sure routes	:	Skin contact				
Speci Resul		÷	Mouse negative				
Resul	L .	•	negative				
	cell mutagenicity						
	assified based on av <b>conents:</b>	allable	information.				
	astatin:						
-	toxicity in vitro	:	Test Type: Rac	terial reverse mutation assay (AMES)			
Geno		•	Result: negative				
			Test Type: Alka Result: negative	aline elution assay			
			-				
			rest type: One	omosomal aberration			





/ersion .6	Revision Date: 2020/03/23	SDS Number: 24360-00015	Date of last issue: 2019/09/13 Date of first issue: 2014/10/21
		Result: nega	ative
		Test Type: I Result: nega	n vitro mammalian cell gene mutation test ative
Genot	oxicity in vivo	: Test Type: M Species: Mo Application I Result: nega	Route: Oral
	cell mutagenicity -	: Weight of ev cell mutager	vidence does not support classification as a germ ח.
Starc	h:		
Genot	oxicity in vitro	: Test Type: E Result: nega	Bacterial reverse mutation assay (AMES) ative
Cellul	ose:		
Genot	oxicity in vitro	: Test Type: E Result: nega	Bacterial reverse mutation assay (AMES) ative
		Test Type: I Result: nega	n vitro mammalian cell gene mutation test ative
Genot	oxicity in vivo	cytogenetic Species: Mc	Route: Ingestion
Citric	acid monohydrate:		
	oxicity in vitro	: Test Type: E Result: nega	Bacterial reverse mutation assay (AMES) ative
		Test Type: in Result: posit	n vitro micronucleus test tive
		Test Type: E Result: nega	Bacterial reverse mutation assay (AMES) ative
Genot	oxicity in vivo	cytogenetic Species: Ra	Route: Ingestion
Titani	um dioxide:		
	oxicity in vitro	: Test Type: E Result: nega	Bacterial reverse mutation assay (AMES) ative
Genot	oxicity in vivo	: Test Type: I	n vivo micronucleus test

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		pecies: Mouse Result: negative	
	1	lesuit. negative	
ogenicity			
ssified based on avai	lable in	formation.	
onents:			
statin:			
6	: N	louse	
(S			ese findings for humans is not certain.
8	: F	lat	
tion Route			
			ese findings for humans is not cortain
13	. 1	The significance of th	
se:			
3			
retime			
		eganve	
m dioxide:			
S			
			ume)
			453
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(S			ode of action may not be relevant in h
	n	nans.	
genicity - Assess-			arcinogenicity in inhalation studies with
luctive toxicity			
-	lable in	formation.	
onents:			
statin:			
on fertility			
			ral
on foetal develop-	: 1	est Type: Embryo-fc	petal development
	statin: stion Route re time Organs Type (s stion Route re time Type (s se: stion Route re time m dioxide: stion Route re time (s source to a sess- luctive toxicity ssified based on avaited on fertility	statin:         s       :       M         tion Route       :       C         Organs       :       H         Type       :       L         Corgans       :       H         Type       :       L         S       :       T         S       :       .       T         S       :       .       .         S       :       .       .         S       :       .       .         S       :       .       .         S       :       .       .         S       :       .       .         S       :       .       .         S       :       .       .         S       :       .       .         M       dioxide:       :       .         S       :       .       .         M       dioxide:       :       .         S       :       .       .         S       :       .       .         ogenicity - Assess-       :       L         a       .       . <td< td=""><td>statin:       Source       Mouse         tion Route       Oral       Oral         retime       -       92 weeks         Organs       Harderian gland         Type       Liver, Lungs         ss       :       Rat         tion Route       :       Oral         retime       :       2 Years         tion Route       :       Oral         retime       :       2 Years         Type       :       Liver, Thyroid         ts       :       The significance of the         se       :       Rat         tion Route       :       Ingestion         retime       :       72 weeks         innegative       :       negative         m dioxide:       :       inhalation (dust/mist/nist/nist/nist/nist/nist/nist/nist/n</td></td<>	statin:       Source       Mouse         tion Route       Oral       Oral         retime       -       92 weeks         Organs       Harderian gland         Type       Liver, Lungs         ss       :       Rat         tion Route       :       Oral         retime       :       2 Years         tion Route       :       Oral         retime       :       2 Years         Type       :       Liver, Thyroid         ts       :       The significance of the         se       :       Rat         tion Route       :       Ingestion         retime       :       72 weeks         innegative       :       negative         m dioxide:       :       inhalation (dust/mist/nist/nist/nist/nist/nist/nist/nist/n

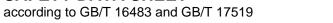
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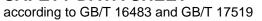
/ersion 1.6	Revision Date: 2020/03/23	SDS Number: 24360-00015	Date of last issue: 2019/09/13 Date of first issue: 2014/10/21					
ment		Application Embryo-foet	Species: Rat Application Route: Oral Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight Result: No teratogenic effects, No adverse effects					
		Species: Ra Application Embryo-foe						
		Species: Ra Application Embryo-foe Result: Tera						
Cellul	ose:							
	s on fertility	Species: Ra	Route: Ingestion					
Effects ment	s on foetal develop-	Species: Ra	Route: Ingestion					
Citric	acid monohydrate:							
	s on foetal develop-	Species: Ra	Route: Ingestion					
	- single exposure assified based on avai	lable information						
	- repeated exposure							
	· ·		ed or repeated exposure.					
<u>Comp</u>	oonents:							
	a <b>statin:</b> t Organs	: Liver, muscl	e, optic nerve, Eye					

Assessment : Causes damage to organs through prolonged or repeated exposure.



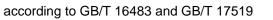


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Repe	ated dose toxicity		
Com	ponents:		
Simv	astatin:		
Speci		: Rat	
NOAE		: 5 mg/kg	
LOAE		: 30 mg/kg	
	cation Route	: Oral	
	sure time et Organs	: 14 - 104 Weeks : Liver, Testis, M	s usculo-skeletal system, Eye
Speci	ies	: Dog	
LOAE		: 10 mg/kg	
Applic	cation Route	: Oral	
	sure time	: 14 - 104 Weeks	3
Targe	et Organs	: Liver, Testis, E	ye
Speci		: Rabbit	
NOA		: 30 mg/kg	
LOAE		: 50 mg/kg	
	cation Route	: Oral	
Targe	et Organs	: Liver, Kidney	
Starc	:h:		
Speci	ies	: Rat	
NOAE		: >= 2,000 mg/kg	]
	cation Route	: Skin contact	
Expo: Metho	sure time	: 28 Days : OECD Test Gu	idaliaa 110
Metho	bu	. OECD Test Gu	
Cellu	lose:		
Speci	ies	: Rat	
NOAE		: >= 9,000 mg/kg	]
	cation Route	: Ingestion	
Expo	sure time	: 90 Days	
Citric	acid monohydrate:		
Speci		: Rat	
NOAE		: 4,000 mg/kg	
LOAE		: 8,000 mg/kg	
	cation Route sure time	: Ingestion : 10 Days	
Exbo:	sure lime	. TO Days	
Titan	ium dioxide:		
Speci		: Rat	
NOA		: 24,000 mg/kg	
	cation Route	: Ingestion	
⊨xpo	sure time	: 28 Days	
Speci	ies	: Rat	





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NOAEL Application Route Exposure time			: 10 mg/m3 : inhalation (dust/mist/fume) : 2 yr				
-	ation toxicity assified based on availa	ble	information.				
Expe	Experience with human exposure						
Comp	oonents:						
Simvastatin: Skin contact Ingestion			Remarks: May produce an allergic reaction. Target Organs: Liver Symptoms: upper respiratory tract infection, Headache, Ak dominal pain, constipation, Nausea Target Organs: Musculo-skeletal system				
ECOLOGICAL INFORMATION							
	,						
	oxicity						
<u>Comp</u>	oonents:						
	<b>astatin:</b> ty to fish	:	LC50 (Pimephale Exposure time: 96 Method: OECD T				
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD T				
Toxici plants	ty to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 96	chneriella subcapitata (green algae)): > 25 6 h			
			NOEC (Pseudokin mg/l Exposure time: 96	rchneriella subcapitata (green algae)): 25 S h			
Toxici	ty to microorganisms	:	EC50: > 30 mg/l Exposure time: 3 Test Type: Respir				
			Method: OECD T	est Guideline 209			
			Method: OECD T NOEC: 21 mg/l Exposure time: 3 Test Type: Respin Method: OECD T	h ation inhibition			
Cellul	l <b>ose:</b> ty to fish		NOEC: 21 mg/l Exposure time: 3 Test Type: Respir Method: OECD T	h ation inhibition			





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			Exposure time: 48 Remarks: Based	3 h on data from similar materials	
	acid monohydrate: ty to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): > 100 mg/l 5 h	
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h		
Titani	ium dioxide:				
	ty to fish	:	LC50 (Oncorhync Exposure time: 96 Method: OECD T		
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48	nagna (Water flea)): > 100 mg/l 3 h	
Toxici plants	ty to algae/aquatic	:	EC50 (Skeletoner Exposure time: 72	ma costatum (marine diatom)): > 10,000 mg 2 h	
Toxici	ty to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Method: OECD T	ĥ	
Persi	stence and degradabil	ity			
<u>Comp</u>	oonents:				
	<b>astatin:</b> gradability	:	Result: rapidly de	gradable	
Stabil	ity in water	:	Hydrolysis: 50 %(3.2 d)		
Cellu	lose:				
Biode	gradability	:	Result: Readily bi	odegradable.	
Citric	acid monohydrate:				
Biode	gradability	:	Result: Readily bi Biodegradation: 9 Exposure time: 28 Method: OECD T	97 %	
Bioac	cumulative potential				
Comp	oonents:				
Partiti	<b>astatin:</b> on coefficient: n- ol/water	:	log Pow: > 4.07		
			15 / 10		

IECSC

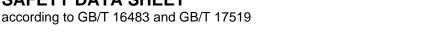


according to GB/T 16483 and GB/T 17519

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Parti	<b>c acid monohydrate:</b> tion coefficient: n- nol/water	: log	Pow: -1.72	
	<b>ility in soil</b> ata available			
	er adverse effects ata available			
13. DISP	OSAL CONSIDERATIO	NS		
Was	osal methods te from residues aminated packaging	: Emj dling	oty container g site for recy	cordance with local regulations. s should be taken to an approved waste han- /cling or disposal. specified: Dispose of as unused product.
14. TRAN	ISPORT INFORMATIO	N		
Inter	national Regulations			
	<b>TDG</b> egulated as a dangerou	s good		
	A-DGR regulated as a dangerou	s good		
	<b>G-Code</b> regulated as a dangerou	s good		
	sport in bulk accordin applicable for product as	-		POL 73/78 and the IBC Code
Nati	onal Regulations			
	<b>5944/12268</b> regulated as a dangerou	s good		
	cial precautions for us applicable	er		
15. REGI	JLATORY INFORMATI	N		
	onal regulatory inform on the Prevention and		of Occupatio	onal Diseases
The AICS	• •		e <b>reported in</b> determined	the following inventories:
DSL		: not	determined	

: not determined





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#### **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 GBZ 2.1-2007	:	USA. ACGIH Threshold Limit Values (TLV) Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.		
ACGIH / TWA GBZ 2.1-2007 / PC-TWA	:	8-hour, time-weighted average Permissible concentration - time weighted average		

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

#### Disclaimer

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



according to GB/T 16483 and GB/T 17519

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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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