

Version 2.5	Revision Date: 02.10.2020		S Number: 998-00014	Date of last issue: 23.03.2020 Date of first issue: 23.01.2015						
1. PRODU	1. PRODUCT AND COMPANY IDENTIFICATION									
Produ	Product name :		Desloratadine Solid Formulation							
Manu	facturer or supplier's	detai	ils							
Comp	any	:	Organon & Co.							
Address		:	30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302							
Telep	hone	:	551-430-6000							
Emerg	gency telephone numbe	er:	215-631-6999							
E-mai	laddress	:	EHSSTEWARD	@organon.com						
Reco	Recommended use of the chemical and restrictions on use									
Recor	nmended use	:	Pharmaceutical							

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Serious eye damage/eye irri- tation	:	Category 1
Carcinogenicity (Inhalation)	:	Category 2
Reproductive toxicity	:	Category 2
Short-term (acute) aquatic hazard	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 3
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H318 Causes serious eye damage. H351 Suspected of causing cancer if inhaled. H361fd Suspected of damaging fertility. Suspected of damag-



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		ing the unborn H412 Harmfu	n child. I to aquatic life with long lasting effects.
Preca	autionary statements	Prevention:	
		P273 Avoid re	read and follow all safety instructions before use. elease to the environment. rotective gloves/ protective clothing/ eye protec- ection.
		with water for sent and easy	+ P338 + P317 IF IN EYES: Immediately rinse several minutes. Remove contact lenses, if pre- / to do. Continue rinsing. Get medical help. sed or concerned, get medical advice.
		Storage: P405 Store lo	
		Disposal: P501 Dispose disposal plant	e of contents/ container to an approved waste

Other hazards which do not result in classification

Contact with dust can cause mechanical irritation or drying of the skin. 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)
Cellulose	9004-34-6	>= 20 - < 30
Desloratadine	100643-71-8	>= 3 - < 5
Talc	14807-96-6	>= 1 - < 5
Titanium dioxide	13463-67-7	>= 1 - < 5

4. FIRST AID MEASURES

General advice	vice immediat	accident or if you feel unwell, seek medical ad- ely. ms persist or in all cases of doubt seek medical
If inhaled	: If inhaled, rem Get medical a	
In case of skin contact	of water. Remove conta Get medical a Wash clothing	ttact, immediately flush skin with soap and plenty aminated clothing and shoes. ttention. before reuse. ean shoes before reuse.
In case of eye contact	: In case of con	tact, immediately flush eyes with plenty of water



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If swallowed Most important symptoms and effects, both acute and delayed		:	for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Causes serious eye damage. Suspected of causing cancer if inhaled. Suspected of damaging fertility. Suspected of damaging the unborn child. Contact with dust can cause mechanical irritation or drying of the skin.					
Protection of first-aiders Notes to physician			:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively.				
	5. FIREFIGHTING MEASURES							
	Unsuita	e extinguishing media able extinguishing	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical None known.				
	media Specifio fighting	c hazards during fire- I	:	concentrations, an 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.			
	Hazard ucts	lous combustion prod-	:	Carbon oxides Metal oxides Oxides of phosph	orus			
	ods	c extinguishing meth-	:	cumstances and t Use water spray t Remove undamag so. Evacuate area.	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			
	Specia for firef	l protective equipment ighters	:		e, wear self-contained breathing apparatus. ective equipment.			

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. 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.



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Methods and materials for containment and cleaning up		:	 Sweep up or vacuum up spillage and collect in suitable of tainer 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 are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and the posal of this material, as well as those materials and item employed in the cleanup of releases. You will need to demine which regulations are applicable. Sections 13 and 15 of this SDS provide information regardered are requirements. 					
7. HANI	DLING AND STORAGE							
Loc	chnical measures cal/Total ventilation vice on safe handling	:	causing an explose Provide adequate and bonding, or in Use only with ade Do not breathe du Do not swallow. Do not get in eyes Avoid prolonged of Handle in accorda practice, based of sessment Keep container tig Minimize dust ger Keep container cl Keep away from h Take precautiona	precautions, such as electrical grounding nert atmospheres. equate ventilation. list. S. or repeated contact with skin. ance with good industrial hygiene and safety in the results of the workplace exposure as-				
Co	nditions for safe storage	:	Keep in properly I Store locked up. Keep tightly close	abelled containers. d. ce with the particular national regulations.				
Ma	terials to avoid	:		the following product types:				

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Desloratadine	100643-71-8	TWA	20 µg/m3 (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal
Talc	14807-96-6	TWA (Res-	2 mg/m3	ACGIH



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				pirable par- ticulate mat- ter)			
Titani	um dioxide		13463-67-7	TŴA	10 mg/m3 (Titanium dioxide)	ACGIH	
Engineering measures :			Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).				
Perso	onal protective equip	ment					
Resp	iratory protection	:	sure assessm	ent demonstrate	ilation is not availab es exposures outside spiratory protection.		
	ter type protection	:	: Particulates type				
Ма	aterial	:	Chemical-resi	stant gloves			
Re	emarks	:	on the concenstance and sp determined fo applications, w chemicals of t	ntration and quar recific to place o r the product. Cl we recommend of he aforementior cturer. Wash ha	ds against chemicals ntity of the hazardou f work. Breakthrough nange gloves often! clarifying the resistar red protective gloves nds before breaks a	s sub- n time is not For special nce to s with the	
Eye p	protection	:	Wear the follo Chemical resi	•			
Skin a	and body protection	:	Select approp sistance data tial. Skin contact n	and an assessn	clothing based on ch nent of the local expo by using impervious	osure poten-	
Hygie	ne measures	:	If exposure to flushing system place. When using d	chemical is like	y during typical use, howers close to the or smoke.		

9. PHYSICAL AND CHEMICAL PROPERTIES

:	powder
:	white
:	No data available
:	No data available
	: : :



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pН		:	No data available	
	lting point/freezing point	:	No data available	
Init	ial boiling point and boiling	-	No data available	
	sh point	:	No data available	9
Ev	aporation rate	:	No data available	2
Fla	ummability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
Fla	mmability (liquids)	:	No data available	9
	per explosion limit / Upper mmability limit	:	No data available	9
	wer explosion limit / Lower mmability limit	:	No data available)
Va	pour pressure	:	No data available	9
Re	lative vapour density	:	No data available	9
Re	lative density	:	No data available	9
De	nsity	:	No data available	9
So	lubility(ies) Water solubility	:	No data available	9
	rtition coefficient: n- anol/water	:	No data available)
	to-ignition temperature	:	No data available)
De	composition temperature	:	No data available)
Vis	cosity Viscosity, dynamic	:	No data available	9
	Viscosity, kinematic	:	No data available)
Ex	plosive properties	:	Not explosive	
Ox	idizing properties	:	The substance or	r mixture is not classified as oxidizing.
Мс	lecular weight	:	No data available)
Pa	rticle size	:	No data available	9



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0. STAB	ILITY AND REACTIVITY	,					
	tivity nical stability ibility of hazardous reac-	:	Stable under r May form expl dling or other	as a reactivity hazard. normal conditions. losive dust-air mixture during processing, han- means. n strong oxidizing agents.			
Conditions to avoid Incompatible materials Hazardous decomposition products		:	 Heat, flames and sparks. Avoid dust formation. Oxidizing agents No hazardous decomposition products are known. 				
1. TOXIC	COLOGICAL INFORMAT		N				
Inforr expo	mation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact				
	e toxicity classified based on availa	ble	information.				
<u>Prod</u> Acute	uct: e oral toxicity	:	Acute toxicity e Method: Calcu	estimate: > 5,000 mg/kg lation method			
<u>Com</u>	ponents:						
Cellu	llose:						
Acute	e oral toxicity	:	LD50 (Rat): > 5	5,000 mg/kg			
Acute	e inhalation toxicity	:	LC50 (Rat): > 5 Exposure time: Test atmosphe	: 4 h			
Acute	e dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg			
Desl	oratadine:						
Acute	e oral toxicity	:	LD50 (Rat): > \$	549 mg/kg			
			LD50 (Mouse):	: 353 mg/kg			
			LD50 (Monkey Symptoms: Vo Remarks: No n				
Talc : Acute	e oral toxicity	:	LD50 (Rat): > 5 Remarks: Base	5,000 mg/kg ed on data from similar materials			
Titan	ium dioxide:						



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Acute oral toxicity		:	LD50 (Rat): > 5,0	00 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				
Not cl	assified based on avail	able	information.		
<u>Comp</u>	oonents:				
	oratadine:				
Speci Resul		:	Rabbit No skin irritation		
Talc:					
Speci Resul		:	Rabbit No skin irritation		
Titani	ium dioxide:				
Speci Resul		:	Rabbit No skin irritation		
	us eye damage/eye irı		ion		
	es serious eye damage ponents:	•			
	pratadine:				
Speci Rema	es	:	Rabbit Severe eye irritati	on	
Talc:					
Speci Resul		:	Rabbit No eye irritation		
Titani	ium dioxide:				
Speci Resul		:	Rabbit No eye irritation		
Respi	iratory or skin sensitis	satio	on		
-	sensitisation assified based on avail	able	information.		
Resp	iratory sensitisation				

Not classified based on available information.



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<u>Com</u>	oonents:		
Deslo	oratadine:		
Test T Expos Speci Resul	sure routes es	: Maximis : Dermal : Guinea p : negative	•
Talc:			
		: Skin con : Humans : negative	
Titani	ium dioxide:		
Test T Expos Speci Resul	sure routes es	: Local lyr : Skin con : Mouse : negative	
<u>Comp</u>	assified based on ava ponents: loso:	ailable informatio	DN.
Cellu Genot	lose: toxicity in vitro		e: Bacterial reverse mutation assay (AMES)
		Result: r Test Typ Result: r	e: In vitro mammalian cell gene mutation test
Genot	toxicity in vivo	cytogene Species:	on Route: Ingestion
Deslo	oratadine:		
	toxicity in vitro	: Test Typ Result: r	e: Bacterial reverse mutation assay (AMES) negative
			e: Chromosomal aberration tem: Human lymphocytes negative
Genot	toxicity in vivo	Species: Cell type	e: Bone marrow on Route: Oral

Talc:



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Genot	oxicity in vitro		A damage and repair, unscheduled DNA syn- nalian cells (in vitro) ′e
Genot	oxicity in vivo	: Test Type: Chi Species: Rat Application Ro Result: negativ	romosome aberration test in vitro ute: Ingestion re
Titani	um dioxide:		
Genot	oxicity in vitro	: Test Type: Bad Result: negativ	cterial reverse mutation assay (AMES) re
Genot	oxicity in vivo	: Test Type: In v Species: Mous Result: negativ	
	nogenicity acted of causing cand	er if inhaled.	
	oonents:		
Cellul	ose:		
Speci	es	: Rat	
	ation Route	: Ingestion	
Resul	sure time t	: 72 weeks : negative	
Deslo	ratadine:		
Speci	es	: Mouse	
Applic	ation Route	: Oral	
•	sure time	: 2 Years	
Resul	L	: negative	
Speci	es	: Rat	
	ation Route	: Oral	
LOAE Resul		: 10 mg/kg body	weight
	t Organs	: equivocal : Liver	
Rema			from similar materials
		The mechanisi mans.	m or mode of action may not be relevant in hu
Talc:			
Speci	es	: Mouse	
Applic	ation Route	: inhalation (dus	t/mist/fume)
Expos Resul	sure time	: 2 Years	
Resul	L	: negative	
	um dioxide:	5.4	
Speci	es	: Rat	



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Ex Me Re	plication Route posure time ethod sult marks	: 2 Years : OECD Test : positive	lust/mist/fume) Guideline 453 nism or mode of action may not be relevant in hu-
Ca	rcinogenicity - Assess- ent	: Limited evic animals.	ence of carcinogenicity in inhalation studies with
	productive toxicity spected of damaging fertili	ty. Suspected of	damaging the unborn child.
<u>Cc</u>	emponents:		
	Ilulose: ects on fertility	Species: Ra	Route: Ingestion
Eff me	ects on foetal develop- ent	Species: Ra	Route: Ingestion
De	sloratadine:		
Eff	ects on fertility	Symptoms: Result: posi	t, male Route: Oral AEL: 12 mg/kg body weight Reduced fertility tive he mechanism or mode of action may not be rele-
			t, female AEL: 3 mg/kg body weight No effects on fertility
Eff me	ects on foetal develop- ent	Species: Ra Application Developme	
		Species: Ra Application Developme	



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			cific developmental abnormalities he mechanism or mode of action may not be rele- ans.
		Species: Ra Application Development	
Repro sessn	oductive toxicity - As- nent	fertility, base	nce of adverse effects on sexual function and ed on animal experiments., Some evidence of ects on development, based on animal experi-
Talc:			
	ts on foetal develop-		Embryo-foetal development
ment		Species: Ra Application Result: nega	Route: Ingestion
STOT Not cl	lassified based on avai - repeated exposure lassified based on avail ated dose toxicity		
Com	ponents:		
Cellu		. Det	
		: Rat : >= 9,000 m : Ingestion : 90 Days	g/kg
Desic	pratadine:		
Speci LOAE Applic Expos	es EL cation Route sure time et Organs		oxicity observed in testing nism or mode of action may not be relevant in hu-
Expos	EL EL cation Route sure time et Organs	: Monkey : 6 mg/kg : 12 mg/kg : Oral : 3 Months : Central nerv : Gastrointes	rous system tinal disturbance



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Expo Rema Spec NOA Appli Expo	EL cation Route sure time arks ies	: Monkey : 6 mg/kg : Oral : 3 Months	int adverse effects were reported tinal disturbance, Fatigue
Spec NOA Appli Expo Spec NOA Appli	EL cation Route sure time ies	: Rat : 24,000 mg/ : Ingestion : 28 Days : Rat : 10 mg/m3 : inhalation (: 2 yr	kg dust/mist/fume)
Not o Expe	ration toxicity classified based on ava erience with human ex ponents:		
Inhal	contact	: Symptoms: : Symptoms:	lay cause respiratory tract irritation. Eye irritation dry mouth, muscle pain, Fatigue, Drowsiness, painful menstration
12. ECOL	OGICAL INFORMATIO	NC	
	oxicity		
	ponents:		
	Ilose: bity to fish	Exposure ti	ias latipes (Japanese medaka)): > 100 mg/l me: 48 h Based on data from similar materials
Desl	oratadine:		
Toxic	sity to fish	: LC50 (Lepo Exposure ti Method: FE	



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	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: FDA 4.08	
Toxici plants	ty to algae/aquatic	:	EC50 (Pseudokir mg/l Exposure time: 72 Method: OECD Te	
			NOEC (Pseudoki mg/l Exposure time: 72 Method: OECD Te	
Toxici	ty to microorganisms	:	EC50 (Natural mid Exposure time: 3 Test Type: Respir Method: OECD To	ation inhibition
			NOEC (Natural m Exposure time: 3 Test Type: Respir Method: OECD Te	ation inhibition
Toxici icity)	ty to fish (Chronic tox-	:	NOEC: 0.12 mg/l Exposure time: 32 Species: Pimepha Method: OECD To	ales promelas (fathead minnow)
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC: 0.48 mg/l Exposure time: 21 Species: Daphnia Method: OECD To	magna (Water flea)
Talc:				
Toxici	ty to fish	:	LC50 (Brachydan Exposure time: 24	io rerio (zebrafish)): > 100,000 mg/l ł h
Titani	ium dioxide:			
Toxici	ty to fish	:	LC50 (Oncorhync Exposure time: 96 Method: OECD To	
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): > 100 mg/l 3 h
Toxici plants	ty to algae/aquatic	:	EC50 (Skeletone mg/l Exposure time: 72	ma costatum (marine diatom)): > 10,000 2 h
Toxici	ty to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Method: OECD Te	h



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Persi	stence and degradabi	lity		
Comp	oonents:			
Cellu	lose:			
Biode	gradability	:	Result: Readily	v biodegradable.
Desic	oratadine:			
Biode	gradability	:	Result: Not rea Biodegradation Exposure time	
			Method: OECI	D Test Guideline 314
			Result: Not rea Biodegradatior	adily biodegradable. n: 0 %
			Exposure time Method: FDA 3	
Stabil	ity in water	:	Hydrolysis: < 1 Method: FDA 3	0 % at50 °C(5 d) 3.09
Bioac	cumulative potential			
<u>Comp</u>	oonents:			
Deslo	oratadine:			
	on coefficient: n- ol/water	:		D Test Guideline 107
Mobil	lity in soil			
<u>Comp</u>	oonents:			
Deslo	oratadine:			
	oution among environ- al compartments	:	log Koc: 3.00 Method: OEC	D Test Guideline 106
	adverse effects Ita available			
DISPO	SAL CONSIDERATIO	NS		
Dispo	osal methods			
Waste	e from residues	:		accordance with local regulations.
Conta	iminated packaging	:	Empty contain dling site for re	ers should be taken to an approved waste h ccycling or disposal. e specified: Dispose of as unused product.
	SPORT INFORMATION			

International Regulations



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•.	IRTDG t regulated as a dangerou	s good							
	IATA-DGR Not regulated as a dangerous good								
	IMDG-Code Not regulated as a dangerous good								
	Transport in bulk according to IMO instruments Not applicable for product as supplied.								
15. RE0	15. REGULATORY INFORMATION								
	Safety, health and environmental regulations/legislation specific for the substance or mix- ture								
Th Alt	• •	oduct are reported in : not determined	the following inventories:						
DS	iL	: not determined							

IECSC : not determined

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/			
Date format	:	dd.mm.yyyy			
Full text of other abbreviations					
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)			
ACGIH / TWA	:	8-hour, time-weighted average			

AIIC - Australian Inventory of Industrial Chemicals; 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



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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IN / EN