

Desogestrel Formulation

Versi 6.1	ion	Revision Date: 2024/04/06		S Number: 970-00027	Date of last issue: 2023/09/26 Date of first issue: 2014/10/15
1. PF	RODUC	T AND COMPANY IDI	ENT	IFICATION	
	Product name		:	Desogestrel Forn	nulation
	Manufacturer or supplier's d		letai	ls	
	Compa	ny	:	Organon & Co.	
	Address		:	JL Raya Pandaaı Pandaan, Jawa T	
	Telepho	one	:	+1-551-430-6000)
	Emerge	ency telephone number	• :	+1-215-631-6999)
	E-mail a	address	:	EHSSTEWARD@	⊉organon.com

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification		
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 1 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate)
Long-term (chronic) aquatic hazard	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	 H360Fd May damage fertility. Suspected of damaging the unborn child. H372 Causes damage to organs (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.





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Precautionary statements

Prevention:

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P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

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

: Mixture

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch, oxidized	65996-62-5	< 10
Titanium dioxide	13463-67-7	< 1
Desogestrel	54024-22-5	>= 0.025 -< 0.25

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.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	 In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse.



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In case of eye contact If swallowed Most important symptoms and effects, both acute and delayed		 Thoroughly clean shoes before reuse. If in eyes, rinse well with water. Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. 				
		: May damage child.	thoroughly with water. fertility. Suspected of damaging the unborn age to organs through prolonged or repeated			
Protec	ction of first-aiders	Contact with o the skin. Dust contact v First Aid respondent	dust can cause mechanical irritation or drying of with the eyes can lead to mechanical irritation. onders should pay attention to self-protection, ecommended personal protective equipment ential for exposure exists (see section 8).			
Notes	to physician		matically and supportively.			
5. FIREFIG	BHTING MEASURES					
Unsui	ble extinguishing media	 Water spray Alcohol-resist Carbon dioxid Dry chemical None known. 				
media Specif fightin	fic hazards during fire-	concentration potential dust	ting dust; fine dust dispersed in air in sufficient s, and in the presence of an ignition source is a explosion hazard. combustion products may be a hazard to health.			
Hazar ucts	dous combustion prod-	: Carbon oxide Nitrogen oxide				
Specif ods	fic extinguishing meth-	cumstances a Use water spi Remove unda so.	hing measures that are appropriate to local cir- and the surrounding environment. ray to cool unopened containers. amaged containers from fire area if it is safe to do			
	al protective equipment fighters		a. f fire, wear self-contained breathing apparatus. protective 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





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Ν	Vethod	s and materials for		nnot be contain veep up or vacu	ed. uum up spillage and collect in suitable con-
с	contain	ment and cleaning up	Av wit Du es lea Lo po em mi Se	h compressed ast deposits sho , as these may used into the atrical or national r sal of this mate aployed in the c ne which regula ctions 13 and 1	dust in the air (i.e., clearing dust surfaces
7. HA		IG AND STORAGE			
Т	Fechnic	cal measures	ca Pre	using an explos	hay accumulate and ignite suspended dust ion. precautions, such as electrical grounding pert atmospheres.
L	_ocal/T	otal ventilation	: Ifs		tion is unavailable, use with local exhaust
F	Advice (on safe handling	: Do Do Av Wa Ha pra se Ke Ke Ta Do Ta	o not get on skir not breathe du o not swallow. oid contact with ash skin thoroug actice, based or ssment ep container tig nimize dust ger ep container cl ep away from h ke precautional o not eat, drink d	eyes. ghly after handling. ance with good industrial hygiene and safety the results of the workplace exposure as-
C	Conditio	ons for safe storage	: Ke Sto Ke	ep in properly l pre locked up. ep tightly close	abelled containers. d. ce with the particular national regulations.
Ν	Vateria	ls to avoid	: Do		the following product types:



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Starch, oxidized	65996-62-5	TWA (inhal- able dust)	0.5 mg/m3	ACGIH
Titanium dioxide	13463-67-7	NAB	10 mg/m3	ID OEL
		o classify these i	fied as carcinogenic t materials as carcinog	
Desogestrel	54024-22-5	TWA	0.04 µg/m3 (OEB 5)	Internal
		Wipe limit	0.4 µg/100 cm ²	Internal

Engineering measures :	Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to pre- vent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment tech- nology designed to prevent leakage of compounds into the workplace.
Personal protective equipment	
Respiratory protection:Filter type:Hand protection	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended 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, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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Hyg	Hygiene measures		 If exposure to chemical is likely during typical use, provey eye flushing systems and safety showers close to the ving place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include revise engineering controls, proper personal protective equipation appropriate degowning and decontamination procedure industrial hygiene monitoring, medical surveillance and use of administrative controls. 			
9. PHYS	ICAL AND CHEMICAL P	ROF	PERTIES			
Арр	earance	:	powder			
Colo	our	:	white			
Odo	bur	:	No data availab	le		
Odo	our Threshold	:	No data availab	le		
pН		:	No data availab	le		
Mel	ting point/freezing point	:	No data availab	le		
Initia ranç	al boiling point and boiling ge	:	No data availat	le		
Flas	sh point	:	Not applicable			
Eva	poration rate	:	Not applicable			
Flar	nmability (solid, gas)	:	May form explo dling or other m	sive dust-air mixture during processing, han- leans.		
Flar	nmability (liquids)	:	No data availab	le		
	per explosion limit / Upper amability limit	:	No data availat	le		
	ver explosion limit / Lower nmability limit	:	No data availat	le		
Vap	our pressure	:	Not applicable			
Rela	ative vapour density	:	Not applicable			
Rela	ative density	:	No data availab	le		
Den	sity	:	No data availab	le		
	ubility(ies) Nater solubility	:	No data availat	le		



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	ion coefficient: n- ol/water	:	Not applicable	
	ignition temperature	:	No data available	
Decor	mposition temperature	:	No data available)
Visco			Not applicable	
	scosity, kinematic		Not applicable	
Explo	sive properties	:	Not explosive	
Oxidiz	Oxidizing properties		The substance o	r mixture is not classified as oxidizing.
	Particle characteristics Particle size		No data available)
IO. STABI	LITY AND REACTIVITY	(
	tivity nical stability bility of hazardous reac-	:	Stable under nor May form explos dling or other me	ve dust-air mixture during processing, han-
Condi	itions to avoid		Heat, flames and Avoid dust forma	
Incompatible materials Hazardous decomposition products		:	Oxidizing agents	composition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of	:	Inhalation
exposure		Skin contact
		Ingestion
		Eye contact

Acute toxicity

Not classified based on available information.

Components:

Titanium dioxide:	
Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
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-



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	tion toxicity	
lestrel·		
	: LD50 (Rat, r	nale and female): > 2,000 mg/kg
	LD50 (Mous	e, male and female): > 2,000 mg/kg
	allable information	
es	: Rabbit	
	: No skin irrita	tion
onents:		
um dioxide:		
	: Rabbit : No eye irrita	tion
ratory or skin sensi	tisation	
-		
assified based on ava	ailable information.	
•		
onents:		
um dioxide:		
		node assay (LLNA)
	: Skin contact : Mouse	
	: negative	
cell mutagenicity		
	ailable information.	
onents:		
um dioxide:		
oxicity in vitro		Bacterial reverse mutation assay (AMES) ative
oxicity in vivo	: Test Type: I	n vivo micronucleus test
	onents: um dioxide: es assified based on ava onents: um dioxide: ensitisation assified based on ava ratory or skin sensi ensitisation assified based on ava ratory sensitisation assified based on ava onents: um dioxide: ype ure routes es cell mutagenicity assified based on ava onents: um dioxide: ype ure routes es	gestrel: oral toxicity : LD50 (Rat, r corrosion/irritation assified based on available information. assified based on available information. onents: um dioxide: ass : assified based on available information. onents: um dioxide: ype : ype : um dioxide: ype : ype : assified based on available information. onents: um dioxide: ype : assified based on available information. onents: um dioxide: ype : ield mutagenicity assified based on available information. onents: um dioxide:



rsion	Revision Date: 2024/04/06	SDS Numbe 21970-0002				
		Species: Result: r				
Deso	gestrel:					
	toxicity in vitro	: Test Typ Result: r	e: Bacterial reverse mutation assay (AMES) negative			
Genotoxicity in vivo		Species: Applicati	: Test Type: Micronucleus test Species: Rat Application Route: Intraperitoneal Result: negative			
	nogenicity lassified based on avai	lable informatio	on.			
<u>Com</u>	ponents:					
Titan	ium dioxide:					
	cation Route sure time od It	: 2 Years : OECD T : positive	n (dust/mist/fume) est Guideline 453 chanism or mode of action may not be relevant in hu			
Carcii ment	nogenicity - Assess-	: Limited evidence of carcinogenicity in inhalation studie animals.				
Deso	gestrel:					
Speci Applic	ies cation Route sure time	: Rat : Oral : 104 wee : negative	-			
	cation Route sure time	: Mouse : Oral : 81 week : negative				
-	oductive toxicity damage fertility. Suspe	cted of damagi	ng the unborn child.			
<u>Com</u>	ponents:					
Deso	gestrel:					
Effects on fertility		Species: Fertility:	e: Fertility/early embryonic development Rabbit, female LOAEL Parent: 2 mg/kg body weight Effects on fertility			



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		Species: Rat,	EL Parent: 0.5 mg/kg body weight
Effects on foetal develop- ment		Species: Rabb Application Ro Developmenta Result: Embry	
		Species: Rat, Application Rc Embryo-foetal weight	
Reproductive toxicity - As- sessment		ity, based on a	e of adverse effects on sexual function and fer animal experiments., Some evidence of advers elopment, based on animal experiments.
	- single exposure assified based on avai	lable information.	
	- repeated exposure		

Causes damage to organs (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) through prolonged or repeated exposure.

Components:

Desogestrel:		
Target Organs	:	Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate
Assessment	:	Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity		
Components:		
Starch, oxidized:		
Species	:	Rat
NOAEL	÷	22,500 mg/kg
Application Route Exposure time	÷	Ingestion 90 Days
	•	
Titanium dioxide:		
Species	:	Rat



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Expos Specie NOAE Applic	ation Route ure time es	 24,000 mg/kg Ingestion 28 Days Rat 10 mg/m3 inhalation (dust/ 2 yr 	mist/fume)
Specie LOAE Applic Expos		: Rat, female : 0.00625 mg/kg : Oral : 26 Weeks : Pituitary gland, l gland	Jterus (including cervix), Ovary, Mammary
Expos		: Rat : 0.005 mg/kg : Oral : 52 Weeks : Pituitary gland, l gland	Jterus (including cervix), Ovary, Mammary
Expos		: Dog : 0.005 mg/kg : Oral : 52 Weeks : Pituitary gland, I gland, Prostate	Jterus (including cervix), Ovary, Mammary

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Desogestrel:

Ingestion

: Symptoms: Headache, changes in libido, Dizziness, Nausea, Vomiting, Diarrhoea, water retention, sodium retention, Gastrointestinal discomfort, mental depression, amenorhea, insomnia, impaired glucose tolerance, pulmonary embolism Target Organs: Uterus (including cervix) Target Organs: Mammary gland



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12. ECOLOGICAL INFORMATION

Ecotoxicity		
Components:		
Titanium dioxide: Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Desogestrel: Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 4 mg/l Exposure time: 96 h Method: FDA 4.11 Remarks: Based on data from similar materials
		LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.3 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 3.9 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility Based on data from similar materials
Toxicity to fish (Chronic tox- icity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.059 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
		NOEC (Oryzias latipes (Japanese medaka)): 0.0000027 mg/l Exposure time: 183 d Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 1.2 mg/l Exposure time: 21 d Remarks: Based on data from similar materials



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Contaminated packaging

ersion .1	Revision Date: 2024/04/06	-	DS Number: 970-00027	Date of last issue: 2023/09/26 Date of first issue: 2014/10/15	
toxicit	ctor (Chronic aquatic y) ity to microorganisms	: :	Remarks: Based NOEC: 70.8 mg/ Exposure time: 3 Test Type: Resp	3 ĥ iration inhibition Test Guideline 209 I on data from similar materials 1 3 h	
Persi	stence and degradabi	lity			
<u>Comp</u>	oonents:				
	Desogestrel: Stability in water		Hydrolysis: < 10 %(5 d) Remarks: Based on data from similar materials		
Bioad	cumulative potential				
Comp	oonents:				
	Desogestrel: Bioaccumulation		Bioconcentration	is macrochirus (Bluegill sunfish) h factor (BCF): 128 I on data from similar materials	
	on coefficient: n- ol/water	:	log Pow: 3.5		
Mobil	lity in soil				
<u>Comp</u>	oonents:				
Distrik	gestrel: oution among environ- al compartments	:	log Koc: 2.84		
	adverse effects Ita available				
3. DISPO	SAL CONSIDERATIO	NS			
-	o sal methods e from residues	:	Do not dispose o	of waste into sewer.	
Conto	Contaminated packaging		Dispose of in ac	cordance with local regulations.	

dling site for recycling or disposal.

Empty containers should be taken to an approved waste han-

:





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			If not otherwise	e specified: Dispose of as unused product.
14. TRAN	ISPORT INFORMATION	1		
Inter	national Regulations			
UN n	UNRTDG UN number Proper shipping name		UN 3077 ENVIRONMEN N.O.S. (Desogestrel)	ITALLY HAZARDOUS SUBSTANCE, SOLID,
Labe	ing group	:	9 III 9 yes	
UN/II	-DGR D No. er shipping name	:	UN 3077 Environmentall (Desogestrel)	y hazardous substance, solid, n.o.s.
Labe Pack	ing group Is ing instruction (cargo	:	9 III Miscellaneous 956	
ger a	ing instruction (passen- ircraft) ronmentally hazardous	:	956 yes	
IMDO UN n	G-Code number er shipping name	:	UN 3077 ENVIRONMEN N.O.S. (Desogestrel)	ITALLY HAZARDOUS SUBSTANCE, SOLID,
Labe EmS	ing group	:	(Desogestrei) 9 III 9 F-A, S-F yes	

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

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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



ersion 1	Revision Date: 2024/04/06	SDS Number: 21970-00027	Date of last issue: 2023/09/26 Date of first issue: 2014/10/15			
ter of	Industry Regulation		PER/4/2013 concerning the Revision of Minis 9/2009 concerning Globally Harmonized Sys- als.			
	lation of the Ministe rdous to Health	r of Health No. 472 o	f 1996 on the Safeguarding of Substances			
Haza	rdous substances that	t must be registered	: Not applicable			
Gove stanc	-	No. 74 of 2001 on the	Management of Hazardous and Toxic Sub-			
Haza	rdous substances app	proved for use	: Not applicable			
Prohil	bited substances		: Not applicable			
Restr	icted substances		: Not applicable			
Regu Mater		y of Trade No. 7 of 20	022 on Distribution and Control of Hazardou			
	Type of hazardous materials subject to distribution and : Not applicable control, Annex I					
	of hazardous materia ol, Annex II	ls subject to distributic	on and : Not applicable			
The c AICS	• •	roduct are reported : not determined	in the following inventories: d			
DSL		: not determine	d			
IECS	С	: not determined	d			
6. OTHE	R INFORMATION					
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Furth	er information					
	ces of key data used to ile the Safety Data t	eChem Portal	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 t	ext of other abbrevia	ations				
ACGI ID OE			Threshold Limit Values (TLV) cupational Exposure Limits			
	H / TWA	· 8-hour time-w	reighted average			



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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 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; TECI - Thailand Existing Chemicals Inventory; 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.

ID / EN