Version



Date of last issue: 2020/10/10

Pancrelipase Formulation

Revision Date:

3.0	2021/04/09		2037-00004	Date of first issue: 2019/11/22
1. PRODU	JCT AND COMPANY ID	ENT	IFICATION	
Chen	nical product name	:	Pancrelipase F	ormulation
	blier's company name, a pany name of supplier		ess and phone Organon & Co.	
Addro	ess	:	30 Hudson Stro Jersey City, Ne	eet, 33nd floor ew Jersey, U.S.A 07302
Telep	phone	:	551-430-6000	
E-ma	ail address	:	EHSSTEWARI	D@organon.com
Emei	rgency telephone numbe	r :	215-631-6999	
	ommended use of the clommended use	-	ical and restric Pharmaceutica	
2. HAZAR	RDS IDENTIFICATION			
	classification of chemi corrosion/irritation	cal :	broduct Category 2	
Serio tatior	bus eye damage/eye irri- N	:	Category 2A	
Resp	iratory sensitisation	:	Category 1	
Shor haza	t-term (acute) aquatic rd	:	Category 2	
	label elements Ird pictograms	:		
Signa	al word	:	Danger	
Haza	rd statements	:		serious eye irritation. se allergy or asthma symptoms or breathing naled.
Preca	autionary statements	:	P264 Wash sk P273 Avoid rel	eathing dust/ fume/ gas/ mist/ vapours/ spray. in thoroughly after handling. ease to the environment. itective gloves/ eye protection/ face protection.

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		P284 Wear res	spiratory protection.	
			F ON SKIN: Wash with plenty of water. F INHALED: Remove person to fresh air and	
		keep comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with v for several minutes. Remove contact lenses, if present ar easy to do. Continue rinsing. P332 + P313 If skin irritation occurs: Get medical advice/ tion. P337 + P313 If eye irritation persists: Get medical advice tention.		
		POISON CEN	f experiencing respiratory symptoms: Call a TER/ doctor. Fake off contaminated clothing and wash it before	
		Disposal: P501 Dispose disposal plant.	of contents/ container to an approved waste	

Other hazards which do not result in classification

Important symptoms and out- : May form combustible dust concentrations in air. lines of the emergency assumed

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Pancrelipase	53608-75-6	>= 50 - < 60	
Starch	9005-25-8	>= 30 - < 40	8-98
Calcium carbonate	471-34-1	>= 1 - < 10	1-122

4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.



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In case of eye contact		:	 Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. 				
If swallowed			Get medical atten	NOT induce vomiting. tion if symptoms occur.			
	nportant symptoms fects, both acute and d	:	ties if inhaled. Excessive exposu other respiratory of	tion.			
	tion of first-aiders	:	First Aid responde and use the recon when the potentia	ers should pay attention to self-protection, nmended personal protective equipment I for exposure exists (see section 8).			
	to physician	:	Treat symptomation	cally and supportively.			
5. FIREFIG	HTING MEASURES						
	le extinguishing media able extinguishing	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical High volume wate	202)			
media Specifi fightino	ic hazards during fire- 9	:	concentrations, ar potential dust exp Do not use a solic fire.	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. I water stream as it may scatter and spread pustion products may be a hazard to health.			
Hazaro ucts	dous combustion prod-	:	Carbon oxides Nitrogen oxides (I Sulphur oxides Metal oxides	NOx)			
ods	ic 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			
for fire	Il protective equipment fighters NTAL RELEASE MEA		Use personal prot	e, wear self-contained breathing apparatus. ective equipment.			

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Use personal protective equipment.
tive equipment and emer-	Follow safe handling advice (see section 7) and personal pro-



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g	ency p	procedures		tective equipment	recommendations (see section 8).
E	Inviron	nmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Local or national posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces
7. HAI	NDLIN	IG AND STORAGE			
н	landlii	ng			

панинну		
Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	
	:	Do not get on skin or clothing.
Advice on safe handling	•	Avoid breathing dust, fume, gas, mist, vapours or spray. Do not swallow.
		Do not get in eyes.
		Wash skin thoroughly after handling.
		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure as-
		Keep container tightly closed.
		Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. 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.
Avoidance of contact	:	Oxidizing agents
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
		When using do not eat, drink or smoke.
		Wash contaminated clothing before re-use.
		The effective operation of a facility should include review of



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		appropriate c industrial hyg	controls, proper personal protective equipment, legowning and decontamination procedures, iene monitoring, medical surveillance and the istrative controls.
Stora	ge		
Condi	itions for safe storage	Keep tightly o	erly labelled containers. closed. rdance with the particular national regulations.
Mater	ials to avoid		with the following product types:
Packa	aging material	: Unsuitable m	aterial: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis		
Pancrelipase	53608-75-6	TWA	OEB 3 (>= 10 < 100 μg/m3)	Internal		
Starch	9005-25-8	TWA	10 mg/m3	ACGIH		
Calcium carbonate	471-34-1	OEL-M (Respirable dust)	2 mg/m3	JP OEL JSOH		
	Further inform	Further information: Class 3 Dust				
		OEL-M (Total dust)	8 mg/m3	JP OEL JSOH		
	Further inform	ation: Class 3 D	ust			

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 equipme	ent	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type Hand 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.



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	Skin ar	nd body protection	:	potential for direct aerosols. Work uniform or la Additional body ga task being perform posable suits) to a	arments should be used based upon the ned (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. legowning techniques to remove potentially					
9. P	9. PHYSICAL AND CHEMICAL PROPERTIES									
	Physica	al state	:	solid						
	Colour		:	No data available	9					
	Odour		:	No data available	9					
	Odour	Threshold	:	No data available	9					
	Melting	point/freezing point	:	No data available	9					
		point, initial boiling nd boiling range	:	No data available	9					
	Flamm	ability (solid, gas)	:	May form combu	stible dust concentrations in air.					
	Flamm	ability (liquids)	:	Not applicable						
	Upper	explosion limit and upp explosion limit / Upper ability limit								
		explosion limit / Lower ability limit	:	No data available						
	Flash p	point	:	Not applicable						
	Decom	position temperature	:	No data available	9					
	рН		:	No data available	9					
	Evapor	ation rate	:	Not applicable						
	Auto-ig	nition temperature	:	No data available	2					
	Viscosi Visc	ity cosity, kinematic	:	Not applicable						
	Solubil Wat	ity(ies) ter solubility	:	No data available						
	Partitio octano	n coefficient: n- I/water	:	Not applicable						



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	Vapour	pressure	:	Not applicable	
	Density and / or relative densi Relative density		ity :	No data available	9
	Density	,	:	No data available	9
	Relative	e vapour density	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	e
	Particle Particle	e characteristics e size	:	No data available	9
10. 9	STABIL	ITY AND REACTIVITY	Y		
		rity cal stability lity of hazardous reac-	:	Stable under nor May form combu	a reactivity hazard. mal conditions. stible dust concentrations in air. rrong oxidizing agents.
	Conditi	ons to avoid	:	Heat, flames and	
		atible materials ous decomposition ts	:	Avoid dust forma Oxidizing agents No hazardous de	
11.	тохісо	LOGICAL INFORMA	TION	l	
	Informa exposu	ation on likely routes of re	f:	Inhalation Skin contact Ingestion Eye contact	
		t oxicity ssified based on availa	able i	nformation.	
	Compo	onents:			
I	_	lipase: pral toxicity	:	LD50 (Rat): > 10,	000 mg/kg
ı I	Starch Acute c	: oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg
		dermal toxicity	:	LD50 (Rabbit): > 2	
1	II Calcium carbonate:				



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Acute	Acute oral toxicity Acute inhalation toxicity			00 mg/kg est Guideline 420 substance or mixture has no acute oral tox-
Acute				h
Acute	e dermal toxicity	:		00 mg/kg est Guideline 402 substance or mixture has no acute dermal
Skin	corrosion/irritation			
Caus	es skin irritation.			
Com	ponents:			
Panc	relipase:			
Spec	ies	:	Rabbit	
Meth		:	OECD Test Guide	eline 404
Resu Rema		:	Skin irritation Based on data fro	om similar materials
Calai	um carbonate:			
			Rabbit	
Spec Meth		:	OECD Test Guide	eline 404
Resu		:	No skin irritation	
Serio	ous eye damage/eye irr	itati	ion	
	es serious eye irritation.			
Com	ponents:			
Panc	relipase:			
Resu	•		Irritation to eves	reversing within 21 days
Rema		:		om similar materials
Starc	:h:			
Spec		:	Rabbit	
Resu		:	No eye irritation	
Calci	um carbonate:			
Spec	ies	:	Rabbit	
Resu	lt	:	No eye irritation	
Metho	od	:	OECD Test Guid	eline 405



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Respi	iratory or skin sensit	isation					
-	Skin sensitisation Not classified based on available information.						
-	Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.						
Comp	oonents:						
Panci	relipase:						
Expos Speci Resul Rema	t	: Inhalation : Humans : positive : Based on data	from similar materials				
Asses	ssment	: May cause sen	sitisation by inhalation.				
Starc	h:						
Test T Expos Speci Resul	sure routes es	: Maximisation T : Skin contact : Guinea pig : negative	est				
Calci	um carbonate:						
Test T Expos Speci Metho Resul	es es	 Local lymph no Skin contact Mouse OECD Test Gu negative 	de assay (LLNA) ideline 429				
	cell mutagenicity assified based on ava	ilable information.					
Comp	oonents:						
Panci	relipase:						
	toxicity in vitro	Method: OECD Result: negativ	terial reverse mutation assay (AMES) Test Guideline 471 e ed on data from similar materials				
		Method: OECD Result: negativ	itro mammalian cell gene mutation test Test Guideline 476 e ed on data from similar materials				
		Method: OECD Result: negativ	omosome aberration test in vitro Test Guideline 473 e ed on data from similar materials				
	h.	Nomaino. Dast					

Starch:



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Genotoxicity in vitro		: Test Type: Bacterial reverse mutation assay (AMES) Result: negative	
Calci	um carbonate:		
Geno	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative	
		Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative	
		Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative	
II Carci	nogenicity		
	lassified based on avai	able information.	
-	oductive toxicity lassified based on avai	able information.	
Com	oonents:		
Panc	relipase:		
	ts on fertility	 Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials 	
Effect ment	ts on foetal develop-	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials	
11			
	um carbonate: ts on fertility	: Test Type: Combined repeated dose toxicity study with t reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative	he
Effect ment	ts on foetal develop-	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative	
II STOT	- single exposure		

STOT - single exposure

Not classified based on available information.



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	r - repeated exposure							
Not c	Not classified based on available information.							
Repe	Repeated dose toxicity							
Com	Components:							
Panc	relipase:							
	EL cation Route sure time od	: Rat : > 100 mg/kg : Ingestion : 13 Weeks : OECD Test Gui : Based on data f	deline 408 rom similar materials					
Starc	h:							
	EL cation Route sure time	: Rat : >= 2,000 mg/kg : Skin contact : 28 Days : OECD Test Gui	deline 410					
Calci	um carbonate:							
	EL cation Route sure time	: Rat : > 1,000 mg/kg : Ingestion : 28 Days : OECD Test Gui	deline 422					
-	Aspiration toxicity Not classified based on available information.							
12. ECOL	OGICAL INFORMATIC	DN .						
Ecoto	oxicity							
Com	ponents:							
Panc	relipase:							
Toxic	ity to fish	: LC50 (Oncorhyr	nchus mykiss (rainbow trout)): > 100 mg/l					

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants		ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l Exposure time: 72 h Method: OECD Test Guideline 201



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		NOEC (Desm Exposure tim Method: OEC	sed on data from similar materials nodesmus subspicatus (green algae)): > 1 mg/l e: 72 h D Test Guideline 201 sed on data from similar materials
II Calciu	um carbonate:		
	ty to fish	Exposure tim Test substand	aynchus mykiss (rainbow trout)): > 100 mg/l e: 96 h ce: Water Accommodated Fraction D Test Guideline 203
	ty to daphnia and other c invertebrates	Exposure tim Test substand	ia magna (Water flea)): > 100 mg/l e: 48 h ce: Water Accommodated Fraction D Test Guideline 202
Toxici plants	ty to algae/aquatic	mg/l Exposure tim Test substand	udokirchneriella subcapitata (green algae)): 50 e: 72 h ce: Water Accommodated Fraction D Test Guideline 201
		mg/l Exposure tim Test substand	okirchneriella subcapitata (green algae)): > 100 e: 72 h ce: Water Accommodated Fraction D Test Guideline 201
Toxici	ty to microorganisms	: NOEC: 1,000 Exposure tim Method: OEC	
		EC50: > 1,00 Exposure tim Method: OEC	5
Persis	stence and degradabil	ity	
Comp	onents:		
	elipase: gradability	: Result: Read	ly biodegradable.
Bioac	cumulative potential		
<u>Comp</u>	onents:		
Partitio	elipase: on coefficient: n- ol/water	: log Pow: < 4	



No dat Hazaro	ty in soil a available						
Not an	dous to the ozone lay	ver					
Not ap	plicable						
	adverse effects a available						
13. DISPOS	SAL CONSIDERATIO	NS					
Waste	sal methods from residues minated packaging	:	Empty containe dling site for rec	ccordance with local regulations. rs should be taken to an approved waste han- cycling or disposal. specified: Dispose of as unused product.			
14. TRANS	PORT INFORMATION	1					
Interna	ational Regulations						
UNRTI	-	s go	od				
	IATA-DGR Not regulated as a dangerous good						
IMDG- Not reç	Code gulated as a dangerou:	s go	od				
•	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.						
	National Regulations Refer to section 15 for specific national regulation.						
15. REGUL	ATORY INFORMATIC	ON					
Relate	d Regulations						
	Fire Service Law Not applicable to dangerous materials / designated flammables.						
Not ap	Chemical Substance Control Law Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.						
Indust	rial Safety and Healtl	n La	w				
	ul Substances Prohil plicable	oited	I from Manufact	ure			
	Harmful Substances Required Permission for Manufacture Not applicable						



ersion 0	Revision Date: 2021/04/09	SDS Number: 5322037-00004	Date of last issue: 2020/10/10 Date of first issue: 2019/11/22				
Substances Prevented From Impairment of Health Not applicable Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Inform on Existing Chemicals having Mutagenicity							
							Not applicable
	Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Inform on Notified Substances having Mutagenicity						
Not a	pplicable						
	tances Subject to be	e Notified Names					
	pplicable						
	tances Subject to be pplicable	e Indicated Names					
	ance on Prevention	of Hazards Due to Sp	pecified Chemical Substances				
	nance on Prevention	of Lead Poisoning					
	ance on Prevention	of Tetraalkyl Lead Po	bisoning				
		of Organic Solvent P	oisoning				
Ordinance on Prevention of Organic Solvent Poisoning Not applicable Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dange Substances)							
					Not applicable		
	phous and Deleterio	us Substances Contro	ol Law				
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the vironment and Promotion of Improvements to the Management Thereof							
Not a	pplicable						
High	Pressure Gas Safet	y Act					
Not a	pplicable						
•	osive Control Law						
	el Safety Law egulated as a dangero	ous good					
Aviat	ion Law	-					
		Disaster Prevention	etc I aw				
	ransportation		as noxious liquid substance				
	transportation		as marine pollutant				
	otics and Psychotro otic or Psychotropic R	pics Control Act aw Material (Export / Ir	nport Permission)				



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Specif	Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable						
	e Disposal and Public rial waste	Cleansing Law					
The c	omponents of this pro	oduct are reported in	the following inventories:				
AICS		: not determined					
DSL		: not determined					
IECSO	>	: not determined					

16. OTHER INFORMATION

Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format	:	yyyy/mm/dd				
Full text of other abbreviations						
ACGIH JP OEL JSOH		USA. ACGIH Threshold Limit Values (TLV) Japan. The Japan Society for Occupational Health. Recom- mendation of Occupational Exposure Limits				
ACGIH / TWA JP OEL JSOH / OEL-M		8-hour, time-weighted average Occupational Exposure Limit-Mean				

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



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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.

JP / EN