

Vers 2.5	sion	Revision Date: 28.03.2024		S Number: 2079-00010	Date of last issue: 30.09.2023 Date of first issue: 22.11.2019
SEC	SECTION 1: IDENTIFICATION Product name			Pancrelipase (Hig	gh / Low Lipase) Formulation
	Manufa	cturer or supplier's d	letai	ls	
	Company			Organon & Co.	
	Address		:	30 Hudson Street Jersey City, New	t, 33nd floor Jersey, U.S.A 07302
	Telepho	one	:	+1-551-430-6000	
	Emergency telephone number		:	+1-215-631-6999	
	E-mail a	address	:	EHSSTEWARD@	lorganon.com
	Recommended use of the ch			cal and restrictio	ons on use
		nended use ions on use	:	Pharmaceutical Not applicable	

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Skin corrosion/irritation	:	Category 2
Serious eye damage/eye irri- tation	:	Category 2A
Respiratory sensitisation	:	Category 1
GHS label elements Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H315 Causes skin irritation. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements	:	Prevention: P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P264 Wash skin thoroughly after handling. P280 Wear protective gloves/ eye protection/ face protection.



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		P284 Wear res	spiratory protection.
		P304 + P340 II keep comfortal P305 + P351 + for several min easy to do. Co P332 + P313 If tion. P337 + P313 If tention. P342 + P311 If POISON CEN	f skin irritation occurs: Get medical advice/ atten f eye irritation persists: Get medical advice/ at- f experiencing respiratory symptoms: Call a
		Disposal:	
		P501 Dispose disposal plant.	of contents/ container to an approved waste
		not result in classifica	tion

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical name	CAS-No.	Concentration (% w/w)
Pancrelipase	53608-75-6	>= 60 -<= 100
Talc	14807-96-6	< 10
Starch	9005-25-8	< 10
Sucrose	57-50-1	< 10
Diethyl phthalate	84-66-2	< 10

SECTION 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. 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. Get medical attention.



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In cas	se of eye contact	 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. 				
lf swa	allowed	Get medical a	ttention. DO NOT induce vomiting. ttention if symptoms occur. thoroughly with water.			
	important symptoms iffects, both acute and ed	 Causes skin irritation. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing diff ties if inhaled. Excessive exposure may aggravate preexisting asthma other respiratory disorders (e.g. emphysema, bronchitis, 				
	ction of first-aiders s to physician	tive airways d First Aid respo and use the re when the pote	ysfunction syndrome). onders should pay attention to self-protection, ecommended personal protective equipment ential for exposure exists (see section 8). matically and supportively.			

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Do not use a solid water stream as it may scatter and spread fire. Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx) Sulphur oxides
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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



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genc	cy procedures		tective equipment	recommendations (see section 8).
Environmental 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		:	over the area to m Add excess liquid Soak up with inert Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Clean up remainin bent. Local or national m posal of this mate employed in the c mine which regula Sections 13 and 1	h absorbents and place a damp covering hinimise entry of the material into the air. to allow the material to enter into solution. t absorbent material. d dust in the air (i.e., clearing dust surfaces air). build not be allowed to accumulate on surfac- form an explosive mixture if they are re- mosphere in sufficient concentration. Ing materials from spill with suitable absor- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements.

SECTION 7. HANDLING AND STORAGE

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 Advice on safe handling	 Use only with adequate ventilation. Do not get on skin or clothing. 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 assessment Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, 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



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Hygiene measures		 environment. 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 					
		engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.					
Conditions for safe storage Materials to avoid		Keep tightly cl Store in accor : Do not store w	Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents				

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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
Talc	14807-96-6	TWA	2.5 mg/m3	AU OEL
		TWA (Res- pirable par- ticulate mat- ter)	2 mg/m3	ACGIH
Starch	9005-25-8	TWA	10 mg/m3	AU OEL
		TWA	10 mg/m3	ACGIH
Sucrose	57-50-1	TWA	10 mg/m3	AU OEL
		TWA	10 mg/m3	ACGIH
Diethyl phthalate	84-66-2	TWA	5 mg/m3	AU OEL
		TWA	5 mg/m3	ACGIH

Components with workplace control parameters

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 containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.



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	ter type protection	:	Combined particu	ulates and organic vapour type
Ма	aterial	:	Chemical-resista	nt gloves
Eye p	marks rotection	:	If the work environ mists or aerosols Wear a faceshiel potential for direct aerosols.	ses with side shields or goggles. Inment or activity involves dusty conditions, , wear the appropriate goggles. d or other full face protection if there is a st contact to the face with dusts, mists, or
Skin a	and body protection	:	task being perfor posable suits) to	arments should be used based upon the med (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. degowning techniques to remove potentially

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable



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		_		_
Re	ative density	•	No data available	9
De	nsity	:	No data available	9
	ubility(ies) Water solubility	:	No data available	e
	rtition coefficient: n- anol/water	:	Not applicable	
	o-ignition temperature	:	No data available	e
De	composition temperature	:	No data available	e
	cosity Viscosity, kinematic	:	Not applicable	
Exp	plosive properties	:	Not explosive	
Ox	idizing properties	:	The substance o	r mixture is not classified as oxidizing.
Мо	lecular weight	:	No data available	9
	ticle characteristics ticle size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form combustible dust concentrations in air. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes	: Inhalation
	Skin contact
	Ingestion
	Eye contact

Acute toxicity

Not classified based on available information.



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Com	ponents:			
Panc	relipase:			
	e oral toxicity	:	LD50 (Rat): > 1	0,000 mg/kg
Talc:				
Acute	e oral toxicity	:	LD50 (Rat): > 5 Remarks: Base	,000 mg/kg d on data from similar materials
Starc				
Acute	e oral toxicity	:	LD50 (Rat): > 5	,000 mg/kg
Acute	e dermal toxicity	:	LD50 (Rabbit): :	> 2,000 mg/kg
Sucr	ose:			
Acute	e oral toxicity	:	LD50 (Rat): 29,	700 mg/kg
Dieth	yl phthalate:			
Acute	e oral toxicity	:	LD50 (Rat): > 5	,000 mg/kg
Acute	e inhalation toxicity	:	LC50 (Rat): > 4 Exposure time: Test atmospher	6 h
Acute	e dermal toxicity	:	LD50 (Rat): > 1	1,181 mg/kg
Skin	corrosion/irritation			
	es skin irritation. ponents:			
	relipase:			
Spec	•	:	Rabbit	
Methe Resu	od	:	OECD Test Gui Skin irritation	deline 404
Resu		:		rom similar materials
Talc:				
Spec Resu		:	Rabbit No skin irritatior	1
Dieth	yl phthalate:			
Spec	ies	:	Rabbit	
Resu	π	:	No skin irritatior	1

Serious eye damage/eye irritation

Causes serious eye irritation.



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<u>Com</u>	oonents:			
	relipase:			
Resul Rema		:		reversing within 21 days om similar materials
Talc:				
Speci Resul		:	Rabbit No eye irritation	
Starc	h:			
Speci Resul		:	Rabbit No eye irritation	
Dieth	yl phthalate:			
Speci		:	Rabbit	
Resul Rema		:	No eye irritation Based on data fr	om similar materials
Resp	iratory or skin sens	itisatic	on	
-	sensitisation			
Not c	lassified based on av	ailable	information.	
-	iratory sensitisation			
-		na sym	ptoms or breathin	g difficulties if inhaled.
Com	oonents:			
	relipase:		labelet's a	
Expos	sure routes	:	Inhalation Humans	
Expos Speci Resul	sure routes es It	:	Humans positive	
Expos Speci	sure routes es It	: : :	Humans positive	om similar materials
Expos Speci Resul Rema	sure routes es It		Humans positive Based on data fr	om similar materials itisation by inhalation.
Expos Speci Resul Rema	sure routes les lt arks	: : : : : : : : : : : : : : : : : : : :	Humans positive Based on data fr	
Expos Speci Resul Rema Asses Talc: Expos	sure routes es lt arks ssment sure routes	::	Humans positive Based on data fr May cause sens Skin contact	
Expos Speci Resul Rema Asses Talc: Expos Speci	sure routes les lt arks ssment sure routes les		Humans positive Based on data fr May cause sens Skin contact Humans	
Expos Speci Resul Rema Asses Talc: Expos	sure routes les lt arks ssment sure routes les		Humans positive Based on data fr May cause sens Skin contact	
Expos Speci Resul Rema Asses Talc: Expos Speci Resul	sure routes les lt arks ssment sure routes les lt h:		Humans positive Based on data fr May cause sens Skin contact Humans negative	itisation by inhalation.
Expos Speci Resul Rema Asses Talc: Expos Speci Resul Starc Test	sure routes les lt arks ssment sure routes les lt h: Type		Humans positive Based on data fr May cause sens Skin contact Humans negative Maximisation Te	itisation by inhalation.
Expos Speci Resul Rema Asses Talc: Expos Speci Resul Starc Test	sure routes les lt arks ssment sure routes les lt h: Type sure routes		Humans positive Based on data fr May cause sens Skin contact Humans negative	itisation by inhalation.



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Dieth	yl phthalate:		
Test 7		: Buehler Test	
Expos Speci	sure routes es	: Skin contact : Guinea pig	
Resul		: negative	
Chro	nic toxicity		
Germ	cell mutagenicity		
Not cl	assified based on av	ailable information.	
<u>Comp</u>	oonents:		
Panc	relipase:		
Geno	toxicity in vitro	Method: OECI Result: negati	
		Remarks: Bas	ed on data from similar materials
			vitro mammalian cell gene mutation test D Test Guideline 476 ve
			ed on data from similar materials
			romosome aberration test in vitro D Test Guideline 473 ve
			ed on data from similar materials
Talc:			
	toxicity in vitro		IA damage and repair, unscheduled DNA sy malian cells (in vitro) ve
Geno	toxicity in vivo	: Test Type: Ch	romosome aberration test in vitro
		Species: Rat Application Ro Result: negati	oute: Ingestion
Starc	h:		
Geno	toxicity in vitro	: Test Type: Ba Result: negati	cterial reverse mutation assay (AMES) ve
Sucro	ose:		
	toxicity in vitro	: Test Type: In Result: negati	vitro mammalian cell gene mutation test ve
Dieth	yl phthalate:		
	toxicity in vitro	: Test Type: Ba	cterial reverse mutation assay (AMES)



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			Method: OECD Result: negativ	e Test Guideline 471
				itro mammalian cell gene mutation test Test Guideline 476 e
				omosome aberration test in vitro Test Guideline 473 e
Carci	nogenicity			
Not cl	assified based on ava	ailable i	nformation.	
<u>Comp</u>	oonents:			
Talc:				
Speci			Mouse	
	ation Route		inhalation (dust	/mist/fume)
Expos	sure time t		2 Years negative	
Resul	·	•	negative	
Dieth	yl phthalate:			
Speci		:	Rat	
	ation Route		Skin contact	
Expos Resul	sure time		103 weeks	
Resul	l	·	negative	
Repro	oductive toxicity			
-	assified based on ava	ailable i	nformation.	
Comp	oonents:			
	relipase:			
	s on fertility		Test Type [.] Two	apparation reproduction toxicity study
	o on formity			-060667000 160100000000 10000000 50000
			Species: Rat	-generation reproduction toxicity study
			Application Rou	ute: Ingestion
			Application Rou Result: negative	ute: Ingestion e
			Application Rou Result: negative	
Effect	s on foetal develop-	:	Application Rou Result: negative Remarks: Base Test Type: Emb	ute: Ingestion e
	s on foetal develop-	:	Application Rou Result: negative Remarks: Base Test Type: Emb Species: Rat	ute: Ingestion e ad on data from similar materials pryo-foetal development
Effect	s on foetal develop-	:	Application Rou Result: negative Remarks: Base Test Type: Emb Species: Rat Application Rou	ute: Ingestion e ed on data from similar materials oryo-foetal development ute: Ingestion
Effect	s on foetal develop-	:	Application Rou Result: negative Remarks: Base Test Type: Emb Species: Rat Application Rou Result: negative	ute: Ingestion e ed on data from similar materials oryo-foetal development ute: Ingestion
Effect	s on foetal develop-	:	Application Rou Result: negative Remarks: Base Test Type: Emb Species: Rat Application Rou Result: negative	ute: Ingestion e ed on data from similar materials oryo-foetal development ute: Ingestion e
Effect ment		:	Application Rou Result: negative Remarks: Base Test Type: Emb Species: Rat Application Rou Result: negative Remarks: Base	ute: Ingestion e ed on data from similar materials pryo-foetal development ute: Ingestion e ed on data from similar materials
Effect ment	s on foetal develop- s on foetal develop-	:	Application Rou Result: negative Remarks: Base Test Type: Emb Species: Rat Application Rou Result: negative Remarks: Base	ute: Ingestion e ed on data from similar materials oryo-foetal development ute: Ingestion e



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			Result: negativ	е
Dieth	yl phthalate:			
Effect	ts on fertility	:	Species: Rat Application Rot	Test Guideline 416
Effect ment	ts on foetal develop-	:	Test Type: Em Species: Rat Application Rou Result: negativ	
			Species: Rabbi	ute: Skin contact
	- single exposure			
	lassified based on ava	ailable	information.	
Not cl STOT	- repeated exposure	e		
Not cl STOT Not cl	- repeated exposure lassified based on ava	e		
Not cl STOT Not cl Repe	 repeated exposure lassified based on availated dose toxicity 	e		
Not cl STOT Not cl Repe <u>Com</u>	 repeated exposure lassified based on availated dose toxicity <u>bonents:</u> 	e		
Not cl STOT Not cl Repe Comp Panc Speci	r - repeated exposure lassified based on ava ated dose toxicity <u>ponents:</u> relipase: les	e		
Not cl STOT Not cl Repe Com Panc Speci NOAE	F - repeated exposure lassified based on ava ated dose toxicity <u>ponents:</u> relipase: les EL	e	information. Rat > 100 mg/kg	
Not cl STOT Not cl Repe Com Panc Speci NOAE Applic	F - repeated exposure lassified based on ava ated dose toxicity ponents: relipase: es EL cation Route	e	information. Rat > 100 mg/kg Ingestion	
Not cl STOT Not cl Repe Com Panc Speci NOAE Applic	7 - repeated exposure lassified based on ava ated dose toxicity ponents: relipase: les EL cation Route sure time	e	information. Rat > 100 mg/kg	ideline 408
Not cl STOT Not cl Repe Comj Panc Speci NOAE Applic Expos	7 - repeated exposure lassified based on ava ated dose toxicity ponents: relipase: les EL cation Route sure time od	e	Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu	ideline 408 from similar materials
Not cl STOT Not cl Repe Comj Panc Speci NOAE Applic Expos Metho	T - repeated exposure lassified based on avainated dose toxicity ponents: relipase: EL cation Route sure time od arks	e	Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu	
Not cl STOT Not cl Repe Comp Panc Speci NOAE Applic Expos Metho Rema Starc Speci	7 - repeated exposure lassified based on avainated dose toxicity ponents: relipase: les EL cation Route sure time od arks h: les	e	information. Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu Based on data Rat	from similar materials
Not cl STOT Not cl Repe Com Panc Speci NOAE Applic Expos Metho Rema Starc Speci NOAE	7 - repeated exposure lassified based on avainated dose toxicity ponents: relipase: les EL cation Route sure time od arks h: les EL	e	information. Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu Based on data Rat >= 2,000 mg/kg	from similar materials
Not cl STOT Not cl Repe Comj Panc Speci NOAE Applic Expos Metho Rema Starc Speci NOAE	repeated exposure lassified based on avainated dose toxicity ponents: relipase: EL cation Route sure time od arks h: es EL cation Route	e	information. Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu Based on data Rat >= 2,000 mg/kg Skin contact	from similar materials
Not cl STOT Not cl Repe Comj Panc Speci NOAE Applic Expos Metho Rema Starc Speci NOAE	repeated exposure lassified based on avainated dose toxicity ponents: relipase: EL cation Route sure time od arks h: les EL cation Route sure time time cation Route sure time	e	information. Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu Based on data Rat >= 2,000 mg/kg	from similar materials
Not cl STOT Not cl Repe Comj Panc Speci NOAE Applic Expos Metho Speci NOAE Applic Expos Metho	repeated exposure lassified based on avainated dose toxicity ponents: relipase: EL cation Route sure time od arks h: les EL cation Route sure time time cation Route sure time	e	information. Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu Based on data Rat >= 2,000 mg/kg Skin contact 28 Days	from similar materials
Not cl STOT Not cl Repe Comj Panc Speci NOAE Applic Expos Metho Speci NOAE Applic Expos Metho	7 - repeated exposure lassified based on avainated dose toxicity ponents: relipase: les EL cation Route sure time od arks h: les EL cation Route sure time od arks h: yl phthalate:	e	information. Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu Based on data Rat >= 2,000 mg/kg Skin contact 28 Days	from similar materials
Not cl STOT Not cl Repe Comj Panc Speci NOAE Applic Expos Metho Rema Starc Speci NOAE Applic Expos Metho Expos Metho Expos Metho Expos NOAE	7 - repeated exposure lassified based on avainated dose toxicity ponents: relipase: les EL cation Route sure time od arks h: les EL cation Route sure time od yl phthalate: les EL	e ailable	information. Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu Based on data Rat >= 2,000 mg/kg Skin contact 28 Days OECD Test Gu Rat 150 mg/kg	from similar materials
Not cl STOT Not cl Repe Comj Panc Speci NOAE Applic Expos Metho Speci NOAE Applic Expos Metho Expos Metho Speci NOAE Applic Expos	7 - repeated exposure lassified based on avainated dose toxicity ponents: relipase: les EL cation Route sure time od arks h: les EL cation Route sure time od arks h: les EL cation Route sure time od arks	e ailable	Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Gu Based on data Rat >= 2,000 mg/kg Skin contact 28 Days OECD Test Gu Rat	from similar materials



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Not c	ration toxicity lassified based on availa			
	oxicity			
<u>Com</u>	ponents:			
Panc	relipase:			
Toxic	ity to fish	:	Exposure time: Method: OECD	nchus mykiss (rainbow trout)): > 100 mg/l 96 h Test Guideline 203 d on data from similar materials
	ity to daphnia and other tic invertebrates	:	Exposure time: Method: OECD	magna (Water flea)): > 10 - 100 mg/l 48 h Test Guideline 202 d on data from similar materials
Toxic plants	ity to algae/aquatic S	:	10 mg/l Exposure time: Method: OECD	kirchneriella subcapitata (green algae)): > 1 72 h Test Guideline 201 d on data from similar materials
			Exposure time: Method: OECD	desmus subspicatus (green algae)): > 1 mg/ 72 h Test Guideline 201 d on data from similar materials
Talc:				
Toxic	ity to fish	:	LC50 (Brachyda Exposure time:	anio rerio (zebrafish)): > 100,000 mg/l 24 h
Dieth	yl phthalate:			
Toxic	ity to fish	:	LC50 (Oncorhy Exposure time:	nchus mykiss (rainbow trout)): 12 mg/l 96 h
	ity to daphnia and other tic invertebrates	:	LC50 (Daphnia Exposure time:	magna (Water flea)): 90 mg/l 48 h
Toxic plants	ity to algae/aquatic S	:	ErC50 (Desmoor Exposure time:	desmus subspicatus (green algae)): 45 mg/l 72 h
			EC10 (Desmod Exposure time:	esmus subspicatus (green algae)): 9 mg/l 72 h
Toxic	ity to fish (Chronic tox-	:	NOEC (Cyprinu	is carpio (Carp)): 5 mg/l



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icity)			Exposure time: 28	3 d	
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)		:	NOEC (Daphnia magna (Water flea)): 25 mg/l Exposure time: 21 d		
Persi	stence and degradabili	ity			
<u>Comp</u>	oonents:				
Panc	relipase:				
Biode	gradability	:	Result: Readily b	odegradable.	
Dioth	vi nhthalato:				
Diethyl phthalate: Biodegradability		:	Result: Readily biodegradable. Biodegradation: 94.6 % Exposure time: 28 d		
Bioad	cumulative potential				
<u>Comp</u>	oonents:				
Panc	relipase:				
Partiti	on coefficient: n- ol/water	:	log Pow: < 4		
Sucro	ose:				
	on coefficient: n- ol/water	:	Pow: < 1		
Partiti	yl phthalate: on coefficient: n- ol/water	:	log Pow: 2.2		
Mobil	ity in soil				
No da	ta available				
	adverse effects				
No da	ita available				

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

SECTION 14. TRANSPORT INFORMATION

International Regulations



Version 2.5	Revision Date: 28.03.2024		DS Number: 22079-00010	Date of last issue: 30.09.2023 Date of first issue: 22.11.2019
Prope Class Subs Pack Labe Envir IATA UN/II Prope Class Subs Pack Labe	umber er shipping name idiary risk ing group ls onmentally hazardous -DGR D No. er shipping name s idiary risk ing group		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
aircra Pack		:	Not applicable	
UN n Prope Class Subs Pack Labe EmS	idiary risk ing group		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	

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

Not applicable for product as supplied.

National Regulations

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Therapeutic Goods (Poisons : No poison schedule number allocated (Please use the original



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Standa	ard) Instrument		•		specific uses, specific conditions or nt apply for this chemical)		
Prohibition/Licensing Requirements			nts	:	There is no applicable prohibition, authorisation and restricted use requirements, including for carcino- gens referred to in Schedule 10 of the model WHS Act and Regula- tions.		
The components of this product are reported in the following inventories:							
AICS	-	:	not determined				
DSL		:	not determined				
IECSC)	:	not determined				

SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date Sources of key data used to compile the Safety Data Sheet	:	28.03.2024 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)				
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Con- taminants.				
ACGIH / TWA	:	8-hour, time-weighted average				
AU OEL / TWA	:	Exposure standard - 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 Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships;



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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.

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