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Trading name:	P.T.A. – P.M.A. REAGENT					
Product code:	PPR-OT-X**	Date of compilation:	21 Dec 2022	Version: 4		

1.1.	Product identifier				
	Trading name:	P.T.A. – P.M	.A. REAGEN	Т	
	Chemical name:	-			
	Catalogue number:	PPR-OT-X*	ŧ		
1.2. Relevant identified uses of the substance or mixture and uses advised against				cture and uses advised against	
	Uses:		For use wi staining ki	th Masson Trichrome and Masson-Goldner Trichrome its.	
	Uses advised against:		Only the id	dentified uses are advised.	
Reason why uses advised against: medical device, registered at the Agency			ict is intended for use only as an <i>in vitro</i> diagnostic evice, registered at the Agency for Medicinal Products and evices and there is no reason to use it for other purposes		
1.3.	Details of the supplier of the safety data sheet				
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:	+3	+385 1 2409997		
	Fax no.:	+3	+385 1 2404039		
	e-mail of competent pe	erson: <u>m</u>	sds@biogno	<u>ost.hr</u>	
	National contact:	-			
1.4.	Emergency telephone i	number			
	National Protection and	d Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	CTION 2 HAZARDS INFORMATION					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification (REGULATION (EC) N	No. 1272/2008	(CLP)			
	Hazard class and category	code:		Hazard statements*:		
	Not identified as hazardous substance					
2.1.2.	Additional information					
	-					
*For ful	l text of Hazard- and EU Hazard-sta	tements: see S	ection 16			
2.2.	Classification according to EC Dire	ective Nr. 1272,	/2008 CLP)			
	Product identification:	P.T.A. – P.M.A	A. REAGENT			
	Identification number:	-				
	Authorization no.:	-				



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	Hazard pictograms:	-			
	Signal word:	-			
	Hazard statements:	-			
	Precautionary statements:	-			
	Further information:	-			
2.3.	Other hazards				
	Endocrine Disrupting Proper	ties:			
	No known endocrine disruptin	g properties			
	Results of PBT and vPvB assessment : According to the results of its assessment, this substance is not PBT or a vPvB.				

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS						
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)		
	-	-	Contains no hazardous substances	-		

SECTIO	ECTION 4 FIRST AID MEASURES					
4.1.	Description of first aid measures					
	General notes:	-				
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.				
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.				
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.				
	Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.				
	Self-protection of the first aider:	Treat symptomatically.				
4.2.	Most important symptoms and e	effects, both acute and delayed				
	FOILOWING INNAISTION.	ccording to our findings, chemical, physical and toxicological properties of e substance have not been entirely tested.				
	FOILOWING CRID COUTSCT.	ccording to our findings, chemical, physical and toxicological properties of e substance have not been entirely tested.				



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	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.			
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.			
4.3.	. Indication of any immedia	Indication of any immediate medical attention and special treatment needed			
	-				

SECTI	SECTION 5 FIREFIGHTING MEASURES				
5.1.	Extinguishing media				
	Suitable extinguishing media: Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam				
	Unsuitable extinguishing media: water jet				
5.2.	Special hazards arising from the substance or mixture				
	Hazardous combustion products: No information available				
5.3.	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.				
5.4.	Additional information				
	Remove sources of heat and ignition.				
	Do not contaminate the environment with extinguishing media.				

SECTIO	SECTION 6 ACCIDENTAL RELEASE MEASURES				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personne				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.			
	Emergency procedures: Mark the area using proper signs.				
6.1.2.	For emergency responders:				
	Wear protective equipment (see Section 8).				
6.2.	Environmental precautions:				
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.				
6.3.	Methods and material for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.			



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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	-	

SECTIO	ON 7 HANDLING AN STORAGE				
7.1.	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:		Keep away from sources of heat and ignition. Do not smoke.		
	Measures to prevent aerosol and dust generat	ion:	Secure proper ventilation.		
	Measures to protect the environment: Other measures:		Prevent spilling into the sewage system and waterways.		
7.1.2.	Advice on general occupational hygiene:				
1.1.6.	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating				
7.2.	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions: Ven		Keep in tightly closed and upright set containers in a we ventilated storage rooms, and away from sources of hear sunlight, and other incompatible substances.		
	Packaging materials:	Ma	nufacturer's original packaging.		
	Paguiroments for storage rooms and vessels:		Keep away from food and drink. Keep the containers tightly closed.		
	Advices for storage equipment:	be dire	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.		
	Further information on storage conditions:	anc che	not place the unused material in the storage room do not use empty containers for storing other emicals. Do not store with incompatible materials (see etion 9).		
7.3.	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	-			



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8.1. Control para	meters				ECTION			
Substance					•	exposure limit term values		
		CAS N	0		,		Biological limit value	
				P	ppm -	mg/m³ -	No information available	
						-	140 IIIIOIIIIatioii availabic	
Substance								
name:								
EC No: -		CAS No:	-					
DNEL								
				Ind	ustrial			
Route of	А	cute		Acute	9	Chronic	Chronic	
exposure: eff		ct local	effe	ect syst	emic	effect loc	al effect systemi	
Oral	-		-			-	-	
Inhalation	-		-			-	-	
Dermal	-		-			-	-	
Critical physical parar	neters: s	olubility, flan	nmabili	ty, corr	osivity:	-		
	1			Con	sumer			
Route of				Acute				
exposure:	effe	ct local	effe	ect syst	emic	effect loc	al effect systemi	
Oral	-		-			-	-	
Inhalation	-		-			-	-	
Dermal	-		-			-	-	
PNEC								
Environmental protection	ction targ	get			PNEC			
Fresh water					No information available			
Freshwater sediment	S					mation availab		
Marine water					No information available			
Marine sediments					No information available			
Food chain					No information available			
Microorganisms in sewage treatment				No information available				
Soil (agricultural)					No information available			
Air					No information available			



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8.2.	Exposure controls					
8.2.1.	Engineering measures					
	Substance/mixture related measures to prevent exposure during identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to prexposure:	event	No information available			
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to pre exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equip	oment				
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) o visor.				
8.2.2.2.	Skin protection					
	Hand protection:		ctive gloves must be according to the EU Directive 2016/425/EEC and ard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min			
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) was sleeves (EN 13034), and shoes that cover the entire foot (EN 10334).				
8.2.2.3.	Respiratory protection:	filter f	ctive full face mask (EN 136) or half mask (EN 140) equipped with a or organic vapors, type "A" (boiling point >65°C) acording to EN) used when concentration levels exceed GVI.			
8.2.2.4.	Thermal hazards:	No inf	ormation available			
8.2.3.	Environmental exposure	controls				
	Substance/mixture related measures to prevent exposure:		See Section 6			
	Structural measures to prevent exposure:		Use modern equipment.			
	Organisational measures to prevent exposure:		Adapt the work process to the required working conditions of the workplace.			
	Technical measures to pre exposure:	event	See Section 6			

SECTI	SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES					
9.1.	Information on basic physical and chemical properties					
		Value	Method			



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Relative vapour density:	No information available	No information available
Density and/or relative density:	No information available	No information available
 Vapour pressure:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Solubility:	No information available	No information available
Kinematic viscosity:	No information available	No information available
pH:	No information available	No information available
Decomposition temperature:	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Flash point:	No information available	No information available
Lover and upper explosion limit:	No information available	No information available
Flammability:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Melting point / freezing point:	No information available	No information available
Odour/odour threshold:	no information available	No information available
Colour:	colourless	No information available

SECTIO	SECTION 10 STABILITY AND REACTIVITY				
10.1.	Reactivity:	See subsections 10.3 through 10.5.			
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.			
10.3.	Possibility of hazardous reactions:	No information available			
10.4.	Conditions to avoid:	No information available			
10.5.	Incompatible materials:	No information available			
10.6.	Hazardous decomposition products:	No information available			

SECTIO	SECTION 11 TOXICOLOGICAL INFORMATION				
11.1.	11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				



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Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-

Specific target organ toxicity – single exposure (STOT SE):							
Specific effects Target organ Note							
Oral exposure:	No information available	No information available	-				
Dermal exposure:	No information available	No information available	-				
Inhalation exposure:	No information available	No information available	-				

Respiratory irritation:	No information available

Irritation and corrosion

	Exposure time	Species	Evaluation	Met hod	Note
Skin irritation:	-	-	-	-	-
Eye irritation:	-	-	-	-	-

Sensitization				
Dermal exposure:	No information available			
Inhalation exposure:	No information available			

Symptoms related to the physical, chemical and toxicological characteristics					
Oral exposure:	No information available				
Dermal exposure:	No information available				
Inhalation exposure:	No information available				
Eye exposure:	No information available				



Chronic oral

No information available

SAFETY DATA SHEET According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

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Repeate	ed dose toxicity (su		onic, chronic	·)	1	
	Dose	Exposure time	Species	Method	Evaluatio	n Note
Subacute oral	No information available	No information available	No informatic available	No information available	No information available	on -
Subacute dermal	No information available	No information available	No informatic available	No information available	No information available	on -
Subacute inhalation	No information available	No information available	No informatic available	No information available	No information available	on -
Subchronic oral	No information available	No information available	No informatic available	No information available	No information available	on -
Subchronic dermal	No information available	No information available	No informatic available	No information available	No information available	on -
Subchronic inhalation	No information available	No information available	No informatic available	No information available	No information	on -
Chronic oral	No information available	No information available	No informatio available	No information available	No information	on -
Chronic dermal	No information available	No information available	No informatic available	No information available	No information available	on -
Chronic inhalation	No information available	No information available	No informatic available	No information available	No information available	on -
Specific	target organ toxic	•	exposure (ST			NI - 4 -
Cubaguta and		Specific effects		Target org	•	Note
		ation available		No information ava		-
Subacute derma		ation available		No information available No information available		-
Subchronic oral		ation available		No information ava		_
Subchronic derm		ation available		No information ava		
Subchronic inhal		ation available		No information ava		_
Subcinonic initiation (No information available)						ļ

No information available



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Chronic dermal No informat		tion available	No information available	-		
Chronic	inhalation	No informa	tion available	No information available	-	
	C) 45 (f	,				
			, mutagenicity, rep	<u> </u>		
	Carcinogenicity: Based on available data, the classification criteria are not met.					
	Mutagenicity	in-vitro:	Based on avail	able data, the classification criteria a	are not met.	
	Genotoxicity:		Based on avail	able data, the classification criteria a	are not met.	
	Mutagenicity	in-vivo:	Based on avail	able data, the classification criteria a	are not met.	
	Germ cell mu	ıtagenicity:	Based on avail	able data, the classification criteria a	are not met.	
	Reproductive	toxicity:	Based on avail	able data, the classification criteria a	are not met.	
11.2	Information of	on other hazard	ls:			
11.2	Information of	on other hazard	ls:			
11.2.1.	Endocrine dis	srupting proper	ties:			
	contain con have endocr according to Commission 2017/2100 c	ance/mixture inponents con rine disrupting o REACH Artic Delegated reg or Commission 05 at levels o	properties cle 57(f) or ulation (EU) Regulation			
	higher.					
11.2.2.	higher. Other inform	ations:				

12.1. Toxicity

Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-



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Microorganisms	LC ₅₀	72 hours	-	–	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	_	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
No information available				

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	рН	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-



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	Bioco	ncentrat	ion factor (BCF)										
V	alue		Species		N	/lethoc		E	valuation			Note	
No info availabl				ation	No info		n		information ilable	on	No infor	mation av	ailable
	Chror	nic ecoto	xicity	1				1					
	Valu	ie	Dose		osure ime	Spe	ecies	V	1ethod		Evaluatio	on	Note
Chronic	toxicit	y on fish	LC ₅₀	No infor availa	mation able	No inforr availa	mation Ible		ormation ilable	1	o informat ailable	ion -	
Chronic toxicity on crustacea (<i>Daphnia</i>)		EC ₅₀		information information i			rmation ilable	1	No information available				
12.4.	Know No in	······································	dicted distributi n available	on in e	environm	nental c	ompart	ment	·S:				
		alue	п. °С	C	oncentra	tion		Me	thod			Note	
	No	mation	No information available	No	informa ^r ilable		No info	orma			-	Note	
	Adso	rption / c	desorption										
Transpo	ort		coefficient 's constant	lc	g Kow		Evap	oratio	on rate		Met	hod	Note
Soil-wat	tor :	No available	information	No ir availa	nformation able	on No	o inform	nation	n available	,	No infor		-
Water-a	air	No available	information	No ir availa	nformation able	on No	o inform	nation	n available		No infori available		-
Soil-air		No available	information	No ir availa	nformation able	on No	o inform	nation	n available)	No informavailable		-



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12.5.	Results of PBT and vPvB assessment									
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.									
12.6.	Endocrine disrupting properties									
	according		t contain components considerer or Commission Delegated regules of 0.1% or higher.			•				
12.7.	()+haradi		Other adverse effects No information available							

SECTION 13 DISPOSAL CONSIDERATIONS

Product/Packaging disposal:

1	13	1	۱۸/	acta	troa	tment	mat	had	c
			V V	สรเษ	пеа	шиеш	11111111	110301	

13 1 1

3	Troducty rackaging disposal.
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature
	Protection.

13.1.2. Waste codes/waste designations according to Law:

No information available

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.

13.1.6. Relevant Community provisions:



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SECTION 14 TRANSPORT INFORMATION	NC						
Transporting/shipment by road	Transporting/shipment by road (ADR)						
UN number:	Not subject to transport regulations.						
UN proper shipping name:	-						
Transport hazard class(es):	-						
Packing group:	-						
Environmentally hazardous:	-						
Special precautions for user:	-						
Transporting/shipment by rail (F	RID)						
UN number:	Not subject to transport regulations.						
UN proper shipping name:	-						
Transport hazard class(es):	-						
Packing group:	-						
Environmentally hazardous:	-						
Special precautions for user:	-						
Inland waterway transport (ADN							
UN number:	Not subject to transport regulations.						
UN proper shipping name:	-						
Transport hazard class(es):	-						
Packing group:	-						
Environmentally hazardous:	-						
Special precautions for user:	-						
Transporting/shipment by sea (I	MDG)						
UN number:	Not subject to transport regulations.						
UN proper shipping name:	-						
Transport hazard class(es):	-						
Packing group:	-						
Environmentally hazardous:	-						
Special precautions for user:	-						
Transporting/shipment by air (IC	CAO-TI/IATA-DGR)						
UN number:	Not subject to transport regulations.						
UN proper shipping name:	-						
Transport hazard class(es):	-						
Packing group:	-						
Environmentally hazardous:	-						



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Special precautions for u	iser: -	
Further information:	-	

SECTI	ON 15 REGULATORY INFO	RMATION			
15.1.	Safety, health and enviror	Safety, health and environmental regulations/legislation specific for the substance or mixture			
	EU regulations				
	Authorization and/or restrictions of use				
	Authorizations: -				
	Restrictions:	-			
		Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;			
	Other EU regulations:	Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;			
		Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;			
		Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;			
		REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);			
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VC guideline)				
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act			
15.2.	Chemical safety assessme	ent			
	None				

SECTION 16 Other information		
16.1. Indication of changes:	-	



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Product code:	PPR-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

16.2. Abbreviations and acronyms:		ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative		
16.3.	Key literature references and source of data:	-		
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classifi	cation	Classification procedure		
-		-		
16.5.	Relevant H statements (numbe	r and full text)		
	H:	-		
16.6.	Training advice: -	-		
16.7.	Further information: \	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

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Exposure scenario resulting to Chemical safety assessment

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