

URIGNOST S KIT

The kit contains:

UriGnost S reagent



SAFETY DATA SHEET According to Regulation (EC) No. 1907/2006

amended by Regulation (EU) No. 1907/2006

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Trading name:	URIGNOST S REAGENT				
Product code:	UGS-OT-X**	Date of compilation:	21 Dec 2022	Version: 4	

1.1.	Product identifier					
	Trading name:	URIGNOST S REAGENT				
	Chemical name:	-				
	Catalogue number:	UGS-X**				
1.2.	Relevant identified use	es of the subs	tance or mi	xture and uses advised against		
	Uses:		Modification rine sedime	acc. to Sternheimer for staining and microscopic analysis of nt.		
	Uses advised against:		only the ider	ntified uses are advised.		
	Reason why uses advis	sea d	evice, regist	is intended for use only as an <i>in vitro</i> diagnostic medical tered at the Agency for Medicinal Products and Medical there is no reason to use it for other purposes		
1.3.	Details of the supplier	Details of the supplier of the safety data sheet				
	Supplier:		BioGnost Ltd.			
	Address:	М	Medjugorska 59, Zagreb			
	Telephone number:	+3	+385 1 2409997			
	Fax no.:	+3	+385 1 2404039			
	e-mail of competent p	erson: <u>m</u>	sds@biogn	<u>ost.hr</u>		
	National contact:	-				
1.4.	Emergency telephone	number				
	National Protection an	d Rescue Dire	ectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:					

SECTIO	TION 2. Hazards identification				
2.1.	Classification of the substance or mixture				
2.1.1.	Classification according to Regulat	tion (EC) No 12	272/2008 (CLP)		
	Hazard class and category code: Hazard statements*:				
	Not identified as hazardous substance				
2.1.2.	Additional information				
	-				
*For ful	ll text of Hazard- and EU Hazard-sta	tements: see S	Section 16		
2.2.	Label elements				
	Product identification:	URIGNOST S	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 Propert	ties:
	No known endocrine disrupting	g properties
	Results of PBT and vPvB asse PBT or a vPvB.	ssment: According to the results of its assessment, this substance is not a

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	SECTION 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	effects, both acute and delayed				
	FOILOWING INDAISTION.	ccording to our findings, chemical, physical and toxicological properties of e substance have not been entirely tested.				
	FOILOWING SKIN CONTACT.	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 immediate medical attention and special treatment needed			
	-			

SECTIO	ECTION 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 Cool closed containers exposed to	compressed air breathing apparatus and fireproof clothing. o fire with water spray or vapor.			
5.4.	Additional information				
	Remove sources of heat and ignition Do not contaminate the environm				

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 the members without protective equipment. Remove all source sparks and ignition. Do not smoke.				
	Emergency procedures: Mark the area using proper signs.				
6.1.2.	For emergency responders:				
	Wear protective equipment (s	ee 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	
	-	

SECTION	ON 7. Handling and 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 generation:	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:					
	Do not eat, drink or smoke in the workspace. T	o 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:	Keep in tightly closed and upright set containers in a we ventilated storage rooms, and away from sources of hea sunlight, and other incompatible substances.				
	Packaging materials:	Manufacturer's original packaging.				
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.				
	Advices for storage equipment:	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:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).				
7.3.	Specific end use(s)					
	Recommendations:	-				
	Industrial sector specific solutions:	-				



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8.1. Control para	meters			tion				
Substance		CAS No			•	l exposure limit rt term values	Biological limit values	
				р	pm	mg/m³		
-		-			-	-	No information available	
Substance - name:								
EC No: -		CAS No:	_					
DNEL								
				Ind	ustrial			
Route of	Ac	ute		Acute		Chronic	Chronic	
exposure:	effec	t local	effe	ect syst	emic	effect local	effect systemic	
Oral	-		-			-	-	
Inhalation -		-			-		-	
Dermal	-		-	-		-	-	
Critical physical parar	neters: so	lubility, fla	ımmabilit	ty, corr	osivity:	-		
				Con	sumer			
Route of		Acute		Acute		Chronic	Chronic	
exposure:	effec	t local	effect sys		emic	effect local	effect systemic	
Oral	-		-			-	-	
Inhalation	-		-		-		-	
Dermal	-		-			-	-	
PNEC								
Environmental protec	tion targe	et			PNEC			
Fresh water					No information available			
Freshwater sediments	5				No information available			
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 infor	mation 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 pr exposure:	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	ment					
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.					
8.2.2.2.	Skin protection						
			tective gloves must be according to the EU Directive 2016/425/EEC and adard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min				
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) with long s (EN 13034), and shoes that cover the entire foot (EN 10335).				
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 of	controls					
	Substance/mixture related measures to prevent expo		See Section 6				
	Structural measures to pr exposure:	event	Use modern equipment.				
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.				
	Technical measures to pre exposure:	event	See Section 6				

SECTIO	SECTION 9. Physical and chemical properties						
9.1.	. Information on basic physical and chemical properties						
	Value Method						



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	Physical state:	liquid	No information available
	Colour:	blue purple	No information available
	Odour/odour threshold:	no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lover and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	рН:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
2.	Other information		

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.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				



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	1							·
Route of exposure:	Method	Speci	es Effec	ive dose or ATE _n	e LD ₅₀ /LC ₅₀	Expos time		Results
Oral exposure:	No informatio available	n _		LD ₅	0	_		-
Dermal exposure:	No informatio available	No information - available		LD ₅	0	-		-
Inhalation exposure:				LC ₅₀)	_		-
:								
Specific target organ toxicity – single exposure (STOT SE):								
	Spe	cific effects	•	Target o	rgan		N	lote
Oral exposure:	No informa	tion available	No inf	ormation	n available	-		
Dermal exposure:	No informa	tion available	No inf	No information available		-		
Inhalation exposu	re: No informa	tion available	No inf	ormation	n available	-		
Respirato	ry irritation:	N	o information	availabl	e			
Irritation	and corrosion							
	Exposure tir	ne Speci	es	Evaluat	ion	Me tho d		Note
Skin irritation:	-	-	-			-	_	
Eye irritation:	-	-	-			-	_	
		i	<u> </u>			i i		
Sensitizat	ion							
Dermal exposure:	No information	available						
Inhalation exposure:	No information	available						
	:							
Symptom	ns related to the ph	ysical, chemica	al and toxicol	ogical ch	naracteristic	S		
Oral exposure:	No informati	on available						
Dermal exposure:	No informati	on available						
Inhalation exposu	·							
Eye exposure:	·							
	1							
Repeated	I dose toxicity (sub	acute, subchro	onic, chronic)					
	Dose	Exposure time	Species	Met	hod	Evalua	tion	Note



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Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	_
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	_
Subchronic oral	No information available	No information available	No information available	No information available	No information available	_
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	_
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	_
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-



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	CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)							
	Carcinogenicity:	Based on available data, the classification criteria are not met.						
	Mutagenicity in-vitro:	Based on available data, the classification criteria are not met.						
	Genotoxicity:	Based on available data, the classification criteria are not met.						
	Mutagenicity <i>in-vivo</i> :	Based on available data, the classification criteria are not met.						
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.						
	Reproductive toxicity:	Based on available data, the classification criteria are not met.						
	2 Information on other hazards:							
11.2	Information on other hazard	ls:						
11.2 11.2.1.	Information on other hazard							
	Endocrine disrupting proper	ties: does not sidered to properties tle 57(f) or ulation (EU) Regulation						

CECTION 1	2 Ecologica	l information

Toxicity 12.1. Exposure Acute toxicity Dose **Species** Method Evaluation Note time No information No information Fish LC_{50} 96 hours available available No information No information EC₅₀ Crustacea: 48 hours available available No information No information Algae/aquatic plants IC_{50} 8 days available available LC_{50} 72 hours Microorganisms Exposure Chronic toxicity Dose Species Method Evaluation Note time No No information No information Fish LC_{50} 96 hours information available available available



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Crustacea:		EC ₅₀	48 hou	urs	No information available		nformation lable	No informa availab		
Algae/aquatio	plant	s IC ₅₀	72 hou	urs	No information available		information lable		No information - available	
Other organis	ms	-	-		-	-		-	-	
12.2. Persi	stence	e and degrada	bility							
		gradation								
	1	egradation ha	lf-lives		Method		Εν	/aluation		Note
Marine water	No	information av	ailable	No	information avai	lable			lable	-
Fresh water	No	information av	ailable	No	o information available No informa		No informa	tion avai	lable	-
Air	No	information av	ailable	No	information avai	lable	No information available		lable	-
Soil	No	information av	ailable	No	No information available		No information available -		-	
% Degradation No information available	n N	Time (day No infor vailable	s) mation	No in	Method nformation able		Evaluation o information ailable	n N	No o informat vailable	ion
Parti	tion co	lative potentia	tanol/w							
Value		centration	рН	°(Evaluati		١	lote
_	No availa	information ble	-	-	No informat available	ion	No informa	tion	-	
		_								
-		tration factor (BCF)							
Bioco	onceni					-				
Bioco Value	oncen	Species	5		Method	E	Evaluation		Note	



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	:				1				
	Chronic ecoto	exicity							
	Value	Dose	Exposure time	Species	Method	Evaluation	Note		
Chroni	c toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-		
	c toxicity on cea (<i>Daphnia</i>)	EC ₅₀	EC ₅₀ No information available		No information available	No information available	-		
		i		i	:		i		
12.4.	Mobility in so	il							
	Known or pre	dicted distribut	ion in environm	ental compar	tments:				
	No information available Surface tension:								
	Value	°C	Concentra	tion	Method		Note		
	No information	No information	No informa	tion No in	formation availa	ble -			

	_			
No information available	No information available	No information available	No information available	-

Adsor	ption /	' deso	rption

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	_
Soil-air	No information available	No information available	No information available	No information available	-

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.



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12.6.	Endocrine disrupting properties			
	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.			
12.7.	Other adverse effects			
	No information available			
SECTIO	N 13. Disposal considerations			
13.1.	Waste treatment methods			
13.1.1.	Product/Packaging 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.			
1215	Other discount or a common deticator			
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:			
	-			
SECTIO	N 14. Transport information			
	Transporting/shipment by road (ADR)			
UN nun	nber: Not subject to transport regulations.			
UN pro	per shipping name: -			
Transpo	ort hazard class(es): -			



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Packing group:		-			
Environmentally ha		-			
Special precautions		-			
	ng/shipment by rail	·····			
UN number:		No	t subject to transport regu	lations.	
UN proper shipping	g name:	-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmentally ha	zardous:	-			
Special precautions	for user:	-			
Inland wat	erway transport (AD	N)			
UN number:		No	t subject to transport regu	lations.	
UN proper shipping	g name:	-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmentally ha	zardous:	-			
Special precautions	for user:	-			
Transporti	ng/shipment by sea	(IMDG)			
UN number:		No	t subject to transport regu	lations.	
UN proper shipping	g name:	-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmentally ha	zardous:	-			
Special precautions	for user:	-			
Transporti	ng/shipment by air (ICAO-T	I/IATA-DGR)		
UN number:		No	t subject to transport regu	lations.	
UN proper shipping	g name:	-			
Transport hazard cl	ass(es):	-			
Packing group: -					
Environmentally hazardous: -		-			
Special precautions	for user:	-			
Further information: -					

SECTION 15. Regulatory information



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15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorization and/or rest	rictions of use			
	Authorizations: -				
	Restrictions:	-			
	Other EU regulations:	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; 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 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-			
	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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Trading name:	URIGNOST S REAGENT				
Product code:	UGS-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 1272/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)		
Classifi	cation	Classification procedure		
_		-		
16.5.	Relevant H statements (numb	er 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