

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

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Trading name:	BUFFER SOLUTION, pH 6.4				
Product code:	PUF64-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

SECTI	ON 1: Identification of	the substance	e/mixture	e and of the company/undertaking	
1.1	Product identifier				
	Trading name:	BUFFER SO	LUTION, p	H 6.4	
	Chemical name:	-			
	Catalogue number:	PUF64-OT-	X**		
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against	
	Uses:		Buffer so	olution for use in hematology, 6 mM.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices 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:		+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent p	erson:	msds@biognost.hr		
	National contact:		-		
1.4	Emergency telephone	Emergency telephone number			
	National Protection ar	nd Rescue Dire	ectorate:	: 112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ON 2. Hazards identification				
2.1	Classification of the substance or mixture				
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)				
	Hazard class and cate	egory code:	Hazard statements*:		
	Not identified as hazardous	substance.	-		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Haza	rd-statements: see	SECTION 16		
2.2	Label elements				
	Product identification:	BUFFER SOLUT	ION, pH 6.4		
	Identification number:	-			
	Authorization number:	-			
	Hazard pictograms:	-			



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	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	Endocrine Disrupting Prope	erties:
	No known endocrine disrupti	ng properties
	<b>Results of PBT and vPvB ass</b> PBT or a vPvB.	sessment: According to the results of its assessment, this substance is not a

SECTION 3. Composition/information on ingredients						
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)		
-	-	-	Contains no hazardous substances.	-		

SECTI	ON 4. First aid measures	
4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and ef	fects, both acute and delayed
	Following inhalation:	No information available.
	Following skin contact:	No information available.
	Following eye contact:	No information available.



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	Following ingestion:	No information available.
4.3	Indication of any immediate medic	al attention and special treatment needed
	-	

SECTION 5. Firefighting measures						
5.1	Extinguishing media	Extinguishing media				
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam				
	Unsuitable extinguishing media:	No information available				
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.				
5.4	Additional information	Additional information				
	Do not contaminate the environment	ent with extinguishing media.				

SECTIO	SECTION 6. Accidental release measures				
6.1	Personal precautions, protective equipment and emergency procedures				
6.1.1.	. For non-emergency personnel				
	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. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.			
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:				
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).				
6.2	Environmental precautions:				
	Do not dispose of in sewage, or Protection and Rescue Director	drainage system and waterways. In case of large spillage contact National orate (NPRD) on 112.			
6.3	Methods and material for con-	tainment and cleaning up			
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.			
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents.			
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).			
6.4	Reference to other sections				



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See Section 7 for information about secure handling.

See Section 8 for information about personal protective equipment.

See Section 13 for information about containment.

SECTIO	ON 7. Handling and storage					
7.1	Precautions for safe handling					
7.1.1.	Protection measures					
	Measures to prevent fire:		Use in well ventilated storage rooms.			
	Measures to prevent aerosol and dust generation	on:	Secure proper ventilation.			
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.			
	Other measures:		-			
7.1.2.	Advice on general occupational hygiene:					
	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 incon	mpatibilities				
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in well ventilated storage roomsat temperatures ranging from 15 to 25 °C.				
	Packaging materials:	Manufact	urer's original packaging.			
	Requirements for storage rooms and vessels:	Keep awa tightly clo	y from food and drink. Keep the containers osed.			
	Advices for storage equipment:	must be r	ge must be made of hard material; floors esistant to chemicals. There must be no drain tly leads into sewage system. Secure proper n.			
	Further information on storage conditions:	Do not place the unused material in the storage roo and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).				
7.3	Specific end use(s)					
	Recommendations:	-				
	Industrial sector specific solutions:	-				

SECTI	SECTION 8. Exposure controls/personal protection									
8.1	Control parameters	Control parameters								
Substance		CAS No	Occupational values/short	exposure limit term values	Biological limit values					
			ppm mg/m³							



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-			-		-	-			-	
Substance name:	-					•				
EC No:	-	CAS No	: -							
DNEL										
				Ind	ustrial					
Route of	Ac	ute	Acut	te		Chro	nic		Chronic	
exposure:	effec	t local	effect sys	stemic		effect l	ocal		effect systemic	
Oral	-		-		-			-		
Inhalation	-		-		-			-		
Dermal	-		-		-			-		
Critical physical pa	rameters:	solubility,	flammabilit	ty, corre	osivity:	-				
				Con	sumer					
Route of	Acute Acute		te	Chronic			Chronic			
exposure:	effe	ect local	effect sys	stemic	ic effect local			effect systemic		
Oral	-		-		-			-		
Inhalation			-		-			-		
Dermal	-		-		-			-		
PNEC										
Environmental pro	tection ta	rget		ı	PNEC					
Fresh water				ا	No information available					
Freshwater sedime	ents			ا	No inforr	nation a	vailable			
Marine water				ı	No information available					
Marine sediments				1	No information available					
Food chain				1	No inforn	nation a	vailable			
Microorganisms in	ı sewage t	reatment		ı	No inforn	nation a	vailable			
Soil (agricultural)				1	No inforr	nation a	vailable			
Air				ا	No inforr	nation a	vailable			
8.2 Expos	sure contro	ols								
8.2.1. Appro	opriate en	gineering	controls							
			d measures identified u	to ses.	•	e equipr			ooms. Use person rink or smoke in t	



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	Structural measures to prevent exposure:		In accordance with Section 7.				
	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.				
	Technical measures to prevent ex	(posure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.				
8.2.2.	Personal protection equipment						
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lowe levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.					
8.2.2.2.	Skin protection						
	Hand protection:	Protec	ective nitrile gloves, 0.11 mm thick (EN 374).				
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.					
8.2.2.3.	Respiratory protection:	Ensure adequate ventilation to the premises where the product stored and/or handled.					
8.2.2.4.	Thermal hazards:	No info	ormation available				
8.2.3.	Environmental exposure controls						
	Substance/mixture related measures to prevent exposure:	See Se	ection 6				
	Structural measures to prevent exposure:	Use m	modern equipment.				
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the lace.				
	Technical measures to prevent exposure:	See Se	ection 6				

SECTI	SECTION 9. Physical and chemical properties								
9.1	Information on basic physical and chemical properties								
		Method							
	Physical state:	liquid	No information available						
	Color:	colourless	No information available						
	Odour/odour threshold:	no odor/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						



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	Lower 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
	pH:	6.35 – 6.45	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
9.2	Other information		
	_		

SECTIO	SECTION 10. Stability and reactivity						
10.1	Reactivity:	No information available					
10.2	Chemical stability:	No information available					
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					

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008										
Acute to	oxicity:									
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results					
Oral:	-	No information available	No information available	No information available	_					
Dermal:	-	No information available	No information available	No information available	_					
Inhalation:	-	No information available	No information available	No information available	_					



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						·		·		
		Specific effects				Target orgar	ı		Note	
Oral:	N	No information available			No infor	mation availa	able	-		
Dermal:	N	o information	available		No infor	mation availa	able	_		
Inhalation:	N	o information	available		No infor	mation availa	able	-		
							,			
Aspiration	on haz	zard:		No infor	mation ava	ailable.				
i i										
Irritation	n and	corrosion								
ī		Exposur	e time	Spec	ies	Evaluation	Method		Note	
Skin corrosion/irritation	on:	-		-	_		-	_		
Serious eye damage/irritation		-		-	-		-	-		
damage/imtation	1									
Sensitiza	ation									
Skin sensitization	n:	-								
Respiratory sensi	itizatio	on: -								
, ,		I								
Sympto	ms rel	ated to the ph	nysical, chem	nical and t	toxicologic	al characteri	istics			
Oral exposure:		No informati								
Dermal exposure	):	No informati	on available							
Inhalation exposi		No informati	on available							
Eye exposure:		No informati	on available							
Repeate	ed dos	e toxicity (sub	acute, subch	ronic, ch	ronic)					
·		Dose	Exposure time	Speci	es	Method	Evaluat	ion	Note	
Subacute oral	No avai	information lable	No information available	No n inforr availa	mation ible	No information available	No informa availabl		-	
Subacute dermal		information lable	No information available	No n inforr availa	mation Ible	No information available	No informa availabl		-	
Subacute inhalation		information lable	No information	No n inforr	mation	No information	No informa	ntion	-	

available

available

available

available



Reproductive toxicity:

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r roduct code.	10	104-01-7	De	ate of compila	tion.	22 DE	C 2022	٧ ر	2131011.
			·				····		φ
Subchronic oral	No information available		No information available	No information available	No infor availa	mation able	No information available	on	-
Subchronic dermal	No availa	information ible	No information available	No information available	No infor availa	mation able	No information available	on	-
Subchronic inhalation	No availa	information ible	No information available	No information available	No infori availa	mation able	No information available	on	-
Chronic oral	No availa	information ible	No information available	No information available	No infori availa	mation able	No information available	on	-
Chronic dermal	No availa	information ible	No information available	No information available	No infori availa	mation able	No information available	on	-
Chronic inhalation	No availa	information able	No information available	No information available	No infori availa	mation able	No information	on	_
	-1		:	·	- 1		i		:
Specific	target	organ toxicit	y – repeated e	xposure (STOT	RE):				
: -			Specific effec	cts		Target o	organ		Note
Subacute oral		No informa	ation available		No in	formatio	n available	-	
Subacute derma	I	No informa	ation available	on available No i		No information available		-	
Subacute inhala	tion	No informa	ation available		No information available		-		
Subchronic oral		No informa	ation available		No information available		-		
Subchronic dern			ation available		No information available		-		
Subchronic inha	lation		ation available		No information available		-		
Chronic oral			ation available				n available	-	
Chronic dermal			ation available		No information available		-		
Chronic inhalation	on	No informa	ation available		No in	formatio	n available	-	
			y; mutagenicity	y; reproductive					
Carcinogenicity:  Mutagenicity <i>in vitro</i> :			No inform						
		n vitro:		No inform					
Genoto		o vivo:		No inform					
	enicity <i>ii</i>				No information available				
Germ C	Germ cell mutagenicity:			INO INTORM	No information available				

No information available



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	Summary of evaluation of the CMR properties:
11.2	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other informations:
	-

12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	4 days	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

#### 12.2 Persistence and degradability



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Abioti	c degr	adation									
	D	egradation h	alf-liv	es	N	Method		Evaluatio	n		Note
Marine water	Noi	information a	ormation available		No information No infavailable available		nformatio able	n	-		
Fresh water	Noi	information a	availak	ole	No inf availal	ormation ole	No ii avail	nformatio able	n	-	
Air	Noi	information a	availab	ole	No inf availal	ormation ole	No ii avail	nformatio able	n	-	
Soil	Noi	information a	availab	ole	No inf availal	ormation ole	No ii avail	nformatio able	n	-	
Biode	aradat	ion									
% Degradati		Time (	davs)		N	Method		Evaluatio	n		Note
No information			nforma	ition		formation	No ii	nformatio		No info	rmation
	ol-wat	etive potentia er partition of entration		- 1	log Kow	/) Method		Evalu	ation		Note
			-		-	_		_		-	
Biocor	ncentra	ation factor (	BCF)								
Value		Speci	es			Method		Evaluati	on		Note
No informatior available		No in available	forma	tion	No information available		No informatio available		on	-	
Chron	ic eco	toxicity					i			•	
Value		Do	se	•	osure ime	Species	N	/lethod	Evalu	uation	Note
		sh LC <sub>50</sub>		No	mation	No information	No info	ormation	No inform	nation	-



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Product	code:	PUF64-OT-X**	Date o	of compilati	ion:	22 Dec	2022	Version:	4
	toxicity on a ( <i>Daphnic</i>	: <b>F</b> ( FA	information i	No information available	No inforn availa	nation ble	No information available	-	
12.4	Mobility in	n soil							
	Known or	predicted distributi	on in environme	ntal compar	tments:				
	No inform	nation available							
	Surface te	ension:							
	Value	°C	Concentrati	on	Meth	od		Note	
	No informatio available	No information available	No information	on No in availa	formation ble	on	-		
	Adsorptio	n / desorption							
Transpor	rt	A/D coefficient lenry's constant	log Kow	Evaporat		N	/lethod	Note	•
Soil-wate	er No avail	information able	No information available	No inforr available	nation	No in availa	formation ble	-	
Water-ai	r No avail	information able	No information available	No inforr available	mation	No in availa	formation ble	-	
Soil-air	No avail	information able	No information available	No inforr available	nation	No in availa	formation ble	_	
12.5.		PBT and vPvB asses			, DDT	. D. D			
	Based on	available data, the p	product does not	contain any	/ PBT Or	VPVB SUI	ostances.		
12.6.	Endocrine	e disrupting propert	es						
	No knowr	n endocrine disrupti	ng properties tha	at affect the	environ	ment.			
12.7.	Other adv	verse effects							
	No advers	se effects are expect	ed.						
SECTION	N 13 Dien	osal consideration	<b>.</b>						
13.1		reatment methods							
.5.1	Traste t	. catheric methods							



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13.1.1.	Product/Packaging dispos	al:
	Submit for disposal to the Protection.	legal person authorized by the Ministry of Environmental and Nature
13.1.2.	Waste codes/waste design	nations according to Law:
	Packaging that contains re	sidual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste treatment – relevan	t information:
	No information available	
13.1.4.	Sewage disposal – relevan	
	Waste must not be dispos	ed of into the sewage system.
13.1.5.	Other disposal recommen	dations:
	authorized by the ministry	duct's remains into the sewage system. Submit the remains to the collectors in charge. Do not dispose of the packaging into the sewage system. Submit ctors authorized by the ministry in charge.
13.1.6.	Relevant Community prov	isions:
	-	
SECTIO	N 14 TRANSPORT INFORM	ATION
	Transporting/shipment by ro	pad (ADR)
UN num	ber:	Not subject to transport regulations
UN prop	er shipping name:	-
Transpo	rt hazard class(es):	-
Packing	group:	-
Environr	mentally hazardous:	-
Special p	orecautions for user:	-
	Transporting/shipment by ra	ail (RID)
UN num	ber:	Not subject to transport regulations
UN prop	er shipping name:	-
Transpo	rt hazard class(es):	-
Packing	group:	-
Environr	nentally hazardous:	-
Special p	orecautions for user:	-
	Inland waterway transport (A	ADN)



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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 (II	MDG)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

SECTION	ECTION 15. Regulatory information							
15.1	Safety, health and env	Safety, health and environmental regulations/legislation specific for the substance or mixture						
	EU regulations							
	Authorization and/or	restrictions of use						
	Authorizations:	-						
	Restrictions:	-						



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	None	
15.2	Chemical safety assessme	ent
	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
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	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 (EC) 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);

SECTIO	ON 16. Other information	
16.1	Indication of changes:	-
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:	-



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

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16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification procedure	
_		-	
16.5.	Relevant H statements (num	ber and full text)	
	H: -	-	
16.6.	Training advice:	-	
		** "X" in the product code marks different volumes (different packagings of the product)	
16.7.	Further information:	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.	

ANNEX: Exposure scenario resulting to chemical safety assessment
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