

# **BIO-DIFF RTU KIT**

The kit contains:

Bio-Diff 1 RTU reagent Bio-Diff 2 RTU reagent Bio-Diff 3 RTU reagent Buffer tablet, pH 6.8 Buffer tablet, pH 7.2



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Trade name:	BIO-DIFF 1 RTU REAGENT				
Product code:	BD1-RTU	Date of compilation:	03.04.2023.	Version:	6

1.1.	Product identifier					
	Trade name:	BIO-DIFF 1 RT	U REAGENT			
	Chemical name:	-				
	Catalogue number:	BD1-RTU				
1.2.	Relevant identified uses of the substance or mixture and uses advised against					
	Uses:	Fixative comp	onent of Bio-Diff RTU kit.			
	Uses advised against:	Only the 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 24099	97			
	Telefax:	+385 1 24040	39			
	e-mail of competent person:	msds@biogno	<u>ost.hr</u>			
	National contact:					
1.4.	Emergency telephone numbers	Emergency telephone numbers				
	National Protection and Rescue	e Directorate:	112			
	Medical information:		+385 1 2348 342			
	Other information:		-			

SECTIO	TON 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 category code: Hazard statement*:					
	Flam. Liq. 2 H225					
	Acute Tox. 3 H301					
	Acute Tox. 3	H311				
	Acute Tox. 3	H331				
	STOT SE 1	H370				
2.1.2.	Additional information					
	-					
* For fu	ull text of Hazard- and EU Hazard-statements: see SECTION 16					
2.2.	Label elements					



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Produ	ct identification:	BIO-DIFF 1 RTU REAGENT					
Identification number:		-					
	prisation number:	-					
Hazar	d pictograms:	GHS02 GHS06					
Signa	l word:	GHS08 V Danger					
	d statements:	H225 Highly flammable liqu H301+H311+H331 Toxic if sv H370 Causes damage to or	vallowed, in contact	with skin or if i	nhaled.		
Preca	utionary statements:	<ul> <li>P210 Keep away from heat ignition sources. No smoking</li> <li>P233 Keep container tightly</li> <li>P280 Wear protective glove protection.</li> <li>P301+P310 IF SWALLOWED:</li> <li>P302+P352 IF ON SKIN: Wash</li> <li>P304+P340 IF INHALED: Rem position comfortable for breat P308+P311 IF exposed or cort</li> </ul>	, hot surfaces, spark , y closed. es, protective clothir Immediately call a Pon n with plenty of soap ove victim to fresh a othing.	ng, eye protect OISON CENTER and water. ir and keep at	ion, face R/doctor. rest in a		
	emetal hazard nation (EU):	-					
2.3. Other	hazards						
Endo	crine Disrupting Pro	operties:					
	iown endocrine disru						
	ts of PBT and vPvB r a vPvB.	assessment: According to the r	esults of its assessm	ent, this substa	ance is not a		



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SECTION 3. Co	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)			
67-56-1/ 200-659-6/ 603-001-00-X	01-2119433307- 44-xxxx	99 %	methanol	Flam. Liq. 2, H225 Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 STOT SE 1, H370			

SECTI	ON 4. First aid measures				
4.1.	Description of first aid n	neasures			
	General notes:	First aider needs to protect himself.			
	Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration, if necessary also oxygen. In case of irregular breathing or respiratory arrest provide artificial respiration.			
	Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap 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 minutes. If the symptoms remain, immediately call in ophthalmolog				
	Following ingestion:	Rinse with water and expectorate. Make the afflicted person drink one glass (100 ml) of 40% ethanol (adult dose). Call a doctor immediately (mention methanol ingestion). Only in exceptional cases, if no medical care is available within one hour, induce vomiting (only in fully conscious persons) and make victim drink ethanol again (approx. 0.3 ml of a 40% alcoholic beverage/kg body weight/hour). Do not attempt to neutralise.			
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.			
4.2.	Most important symptoms and effects, both acute and delayed				
	Following inhalation:	Irritation to the airways and possible damage to the lung probably only through very high vapor concentrations, then even absorptive-toxic effects.			
	Following skin contact:	Minor/no irritation, degreasing action, following massive contact watch for danger of skin absorption and possibly delayed onset of systemic effects.			
	Following eye contact:	Slight through to moderate irritation due to the liquid and concentrated vapors, conjunctivitis, later chemosis, apparently minor probability of cornea damage, later occurring visual disturbances are caused not primarily through local contact but are systemically related (following absorption).			
	Following ingestion:	Stomach and bowel irritation, feeling unwell, nausea, vomiting, strong abdominal pain. Absorption may cause toxic effects.			



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4.3. Indication of any immediate medical attention and special treatment needed

SECTIO	TION 5. Firefighting measures				
5.1.	Extinguishing media				
	Suitable extinguishing media:	water spray, foam, dry powder, CO <sub>2</sub>			
	Unsuitable extinguishing media:	No information available			
5.2.	Special hazards arising from the sub	ostance or mixture			
	Hazardous by products of fire:	Combustible. Vapours are heavier than air and may spread along floors. Forms explosive mixtures with air at ambient temperatures. Development of hazardous combustion gases or vapours possible in the event of fire.			
5.3.	Advice for firefighters				
	Stay in danger area only with self-conditional distance or by wearing suitable pro-	ontained breathing apparatus. Prevent skin contact by keeping a safe tective clothing.			
5.4.	Additional information	Additional information			
	Remove container from danger zon contaminating surface water or the	e and cool with water. Prevent fire extinguishing water from ground water system.			

SECTIO	ION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency pe	rsonnel			
	Protective equipment:		Use personal protective equipment (see Section 8).		
	Accident prevention methods:		Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.s		
	Emergency procedures: Mark the area using proper signs.				
6.1.2.	For emergency respon	ders:			
	Use protective equipm (see Section 8).	ent; in case c	of inadequate ventilation use adequate airways protective equipment		
6.2.	Environmental precaut	ions:			
	Do not let product ent	er drains. Ris	k of explosion.		
6.3.	Methods and materials for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	capping Cover drains. Collect, bind and pump off spills.			



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6.3.2.	For cleaning: Where possible, the substance can be absorbed by using inflammable impermeable containers. Store the substance in well ventilated storage until disposal. Submit for disposal to the legal persons authorized by th of Environmental and Nature Protection. After disposal of the products area and and involved materials with water.		ghtly closed ge rooms the Ministry				
6.3.3.	Other info	rmation: Do not use tools that may cause sparks.					
6.4.	Reference	nce to other sections					
	See Section 7 for information on safe handling.						

See Section 8 for information on personal protective equipment.

See Section 13 for disposal information.

SECTIO	DN 7. Handling and storage					
7.1.	Precautions for safe handling					
7.1.1.	Protection measures	rotection measures				
	Measures for fire prevention:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition and direct sunlight. Do not smoke. Take precautionary measures against static discharge.				
	Measures for preventing spray and dust formation	n: Secure proper ventilation. Prevent formation of aerosols.				
	Environmental precautions:	Prevent spilling into the sewage system and waterways.				
	Other measures:	Protect against electrostatic charges.				
7.1.2.	Advice on general occupational hygiene:					
	Do not eat, drink or smoke in the workspace. Tho	roughly wash hands after work and before eating.				
7.2.	Conditions for safe storage, including any incomp	atibilities				
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, 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.				



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Furthe	r information on sto	rage conditions:	and do chemic	place the unused m not use empty cont cals. Do not store wit oction 10).	ainers for stori	ing other		
7.3. Specif	ic end use(s)							
Recor	nmendations:		-					
Indust	rial sector specific so	olutions:	-					

SECTION 8. Exposu	re contro	ols/persona	l protec	tion			
8.1. Control para	ameters						
Substance CAS N		Occupational ex No values/short t				iological limit values	
				ppm	mg/m <sup>3</sup>		-
Methanol 67-56		5-1	200	260	(7.0 mg/	nol/mol of creatinine* /g of creatinine*), •shift urinary excretion	
* For all results perta consideration	ining cre	atinine leve	ls, creatir	nine concentration	on < 0.5 g/l an	d > 3.0 g/	l may not be taken into
Substance: -							
EC No: -		CAS No:	-				
DNEL					L		
				Industrial			
Route of	ļ	Acute	Acute		Chronic		Chronic
exposure:	effe	ect local	effe	ect systemic	effect local		effect systemic
Oral	-		-		-		-
Inhalation	260 m	50 mg/m <sup>3</sup> 260 mg		J∕m³	260 mg/m <sup>3</sup>		$260 \text{ mm} \text{ m}^3 (\text{mm} \text{ sth} \text{ mm} \text{ s})$
Innalation	(metha	anol) (metha		nol)	(methanol)		260 mg/m <sup>3</sup> (methanol)
Dermal	-		40 mg/	'kg (methanol)			40 mg/kg (methanol)
Critical physical para	meters: s	solubility, fla	mmability, corrosivity:		-		
				Consumer			
Route of	A	Acute		Acute	Chron	ic	Chronic
exposure:	effe	ect local	effe	ect systemic	effect lo	ocal	effect systemic
Oral	-		8 mg/k	g (methanol)	-		8 mg/kg (methanol)
Inhalation	50 mg	/m <sup>3</sup>	50 mg/	′m <sup>3</sup>	50 mg/m <sup>3</sup>		50 mg/m <sup>3</sup>
	(metha	anol)	(metha	nol)	(methanol)		(methanol)
Dermal	-		8 mg/k	g (methanol)			8 mg/kg (methanol)
PNEC							



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Environm	ental protection target		PNEC		
Fresh wat	ter		154 mg/l (methanol)		
Freshwat	er sediments		570.4 mg/kg (methanol)		
Marine w	rater		15.4 mg/l (methanol)		
Marine se	ediments		No information available		
Food chain			No information available		
Microorganisms in sewage treatment			100 mg/l (methanol)		
Soil (agri	cultural)		23.5 mg/kg (methanol)		
Air			No information available		
8.2.	Exposure controls				
8.2.1.	Appropriate engineering measures	Appropriate engineering measures			
Substance/mixture related measures to prevent exposure		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the			

0.2.1.	Appropriate 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 prevent exposure:	No information available				
Organisational measures to prevent exposure:		Organization of work in order to reduce other worker's influence during work process.				
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.				
8.2.2.	Personal protection equipment					
8.2.2.1.	Eye and face protection:	Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).				
8.2.2.2.	Skin protection:					
	Hand protection:	The protective gloves to be used must comply with the specification of EC Directive 2016/425 and the related standard EN374. Full contact: Glove material: butyl rubber Glove thickness: 0.70 mm				
		Break through time: > 480 min Splash contact: Gloves material: viton (R) Glove thickness: 0.70 mm Break through time: > 120 min				



exposure:

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	Other	skin protection:		The type of prote the concentration	atic suit protecting a ective equipment m on and amount of t splace and shoes that	ust be selected he dangerous	according to substance at	
8.2.2.3.	Respi	ratory protection:	atory protection: testing of re		ired when vapours/aerosols are generated. Recommended type: gas filter AX, colour code brown (EN 371). The peneur has to ensure that maintenance, cleaning and og of respiratory protective devices are carried out rding to the instructions of the producer.			
8.2.2.4.	Thern	nal hazards:		No information a	available			
8.2.3.	Enviro	vironmental exposure controls						
		ance/mixture related ures to prevent expos		See Section 6				
		ctural measures to prevent osure:		Use modern equipment. Do not let product enter drains. Risk o explosion.				
		anisational measures to prevent osure:		Adapt the work process to the required working conditions of the workplace.				
	Techr	nical measures to prev	vent	See Section 6				

See Section 6

.1.	Information on basic physical and chemical properties						
		Value	Method				
	Physical state:	liquid	No information available				
	Colour:	colourless	No information available				
	Odour/odour threshold:	methanol like/no information available	No information available				
	Melting point / freezing point:	-98 ℃	No information available				
	Boiling point or initial boiling point and boiling range:	65 °C (at 1.013 hPa)	No information available				
	Flammability:	No information available	No information available				
	Lower and upper explosion limit:	lower: 6 % (V) methanol upper: 36.5 % (V) methanol	No information available				
	Flash point:	12 °C	No information available				
	Auto-ignition temperature:	No information available	No information available				
	Decomposition temperature:	No information available	No information available				
	pH:	No information available	No information available				
	Kinematic viscosity:	No information available	No information available				
	Solubility:	No information available	No information available				



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				ruge	5 01 10
Trade name: Product code: BD1-RTU		BIO-DIFF 1 RT	U REAGENT		
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Dartit	on coefficient n-				
	ol/water (log value):	No information available	e No ir	No information available	
Vapour pressure:		128 hPa (20 °C)	No ir	No information available	
Density and/or relative density		0.79 (20 °C)	No ir	No information available	
Relati	ve vapour density:	No information available	e No ir	No information available	
Partic	le characteristics:	No information available	a No ir	No information available	

	Particle characteristics:	No information available	No information available
9.2.	Other information		
	Ignition temperature: 455 °C		

SECTIC	SECTION 10.: Stability and reactivity						
10.1.	Reactivity:	Vapours may form explosive mixture with air.					
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).					
		Risk of explosion with: Oxidizing agents, alkali metals, nitric acid, sulphuric acid, hydrogen peroxide, permanganic acid, sodium hypochlorite.					
10.3.	Possibility of hazardous reactions:	The substance can react dangerously with: halogens, oxidizing agents, reducing agents, acids, acetyl bromide, alkylaluminium solutions, beryllium hydride, chloroform, chromium (VI)-oxide, cyanuric chloride, alkaline-earth metals, magnesium splinters, phosphorus trioxide, Raney-nickel/hydrogenation, acid anhydrides, acid halogenides, tetrachloromethane/light metals.					
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.					
10.5.	Incompatible materials:	Various plastics, magnesium, zinc alloys, aluminium and galvanised iron.					
10.6.	Hazardous decomposition products:	No information available.					

SECTION 11. Tox	SECTION 11. Toxicological information							
11.1. Informat	11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008							
Acute to	Acute toxicity:							
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results			
Oral:	No information available	rat	LD <sub>50</sub>	-	125.13 mg/kg (methanol)			
Dermal:	No information available	rabbit	LD <sub>50</sub>	-	375.13 mg/kg (methanol)			



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Trade name:	BIO-DIFF 1 RTU REAGENT							
Product code:	BD1-RTU	Date of co	mpilation:	03.04.2023.	Version:	6		
Inhalation:	No informatio available	n rat	LC	50 4	h	38 mg/l ethanol)		
Specific	target organ toxicit	v - sinale exposu	re (STOT-SF):					
	<u> </u>	ific effects		Target organ	1	Note		
Oral:	No information a			mation available	e -			
Dermal:	No information a	vailable	No info	mation availabl	e -			
Inhalation:	No information a	vailable	Eyes		mixture ca damage t			
Aspiratio	on hazard:	No i	nformation avai	lable				
Irritation	and corrosion							
	Exposure	time Spe	cies Evalua	ation Metho	d N	ote		
Skin corrosion/irritatic	n -	-	-	-	drying-out e resulting in chapped ski	rough and		
Serious eye damage/irritation	-	-	-	-	irritations of membranes			
Sensitiza								
Skin sensitization Respiratory sensitization:	No informati	use sensitization. ion available						
	1							
Symptor	ns related to the pl		5					
Oral exposure:	Stomach and bov abdominal pain. A		•	•		5 5		
Dermal exposure:	Minimum level of possibility of dela		5. 5	exposure may ca	use absorption a	nd greater		
Inhalation exposure:	Airways irritation drowsiness, head				vapor concentrat	ion, dizziness		
Eye exposure:	Mild to moderate cornea damage,b occur later, after t	lindness, irreversi	• •		•	•		
Deneste	d doco tovicity (	acuto cubebra:	c chronic)					
кереате	d dose toxicity (sub Dose	Exposure time	c, chronic) Species			1		



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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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	CMD offects (carcinegenicity mutagenicity re	productive toxicity)
	CMR effects (carcinogenicity, mutagenicity, re	· · · · · ·
	Carcinogenicity:	No information available
	Mutagenicity in-vitro:	No information available
	Genotoxicity:	No information available
	Mutagenicity <i>in-vivo</i> :	No information available
	Germ cell mutagenicity:	No information available
	Reproductive toxicity:	No information available
	Summary of evaluation of the CMR properties:	No information available
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 information:	
	-	

SECTION 12. Ecologi	cal inforn	nation				
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	Lepomis macrochirus (Bluegill sunfish)	No information available	No information available	15.400 mg/l (methanol)
Crustacea:	EC <sub>50</sub>	48 hours	Daphnia magna	No information available	No information available	>18.260 mg/l (methanol)
Algae/aquatic plants:	IC <sub>50</sub>	8 days	Pseudokirchneriella subcapitata (green algae)	No information available	No information available	22.000 mg/l (methanol)
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	-



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Crustacea:		EC <sub>50</sub>	48 hours	No in availa	formation ble				mation -		
Algae/aquatic plants:		IC <sub>50</sub>	72 hours		No information available No No information available available			-			
Other organis	ns	-	-	-		-		_		-	
12.2. Persis	tence	and degrada	ability								
Abiot	ic deg	radation					1				Ĩ
		egradation h			Method				luation		Note
Marine water		nformation a			formation avai			format			-
Fresh water	No ii	nformation a	vailable	No in	formation avai	lable		format			-
Air	No ii	nformation a	vailable	ble No information available No information				on ava	ilable	-	
Soil	No ii	nformation a	vailable	No information available No informa		format	on ava	ilable	-		
Biode	grada	tion									
% Degradation	-	Time (da	ays)	Ν	/lethod	E١	aluatio	n		No	te
-		-	-			No inf availat	ormatio ble	on	-		
12.3. Bioac	cumul	ative potenti	al			-					
Octar	nol-wa	ter partition	coefficient	(log Kov	N)						
Value	Con	centration	рН	°C	Method		Evalua	ntion		N	ote
_	No availat	information ble	-	-	-		inform ailable	ation	-		
Віосо	ncenti	ration Factor	(BCF)								
Value		Spec	ies		Method	E	valuatio	on		No	te
No informatio available		No informat available	ion	No in <sup>.</sup> availa	formation ble	No inf availal	ormatio ple	on	No ir availa	nformat able	ion



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	Val	ue	Dose	Exposure time		Species	Me	thod	Evalu	ation	Note
Chronic	c toxici	ty on fish	LC <sub>50</sub>	No information available		o formation /ailable	No inform availal		No inforr available	nation	-
Chronic crustac		•	EC <sub>50</sub>	No information available		o formation ⁄ailable	No inform availal		No inforr available	nation	-
12.4.	Mob	ility in soil									
	Knov	vn or predicte	d distributi	on in enviro	nmen	tal compartn	nents:				
	No ir	nformation av	ailable								
	Surfa	ace tension:									
		Value	c	C		Concentrati	on		Metho	b	Note
	No avail	information able	No ir available	nformation	No ir	nformation a	vailable No information		ormation a	vailable	-
	Adsc	orption / deso	rption								
Transpo		A/D coef Henry's cc	ficient	log Ko	w	Evaporatio	on rate	Me	ethod	No	ote
Soil-Wa	ater	No in available	formation	No inform available	ation	No informa available	ation	No info availabl		-	
Water-	Air	No in available	formation	No inform available	ation	No informa available	ation	No info availabl	formation -		
Soil-Air	•	No in available	formation	No inform available	ation	No informa available	ation	No info availabl		-	
10 5	<b>D</b>										
12.5.		Its of PBT and				autorita f					
12.0		tance(s) in the			eet the	criteria for	PBI or vi	νB			
12.6.		ocrine disrupti	<u> </u>				1 1.		, <u>.</u>		
	ассо	substance/mix rding to REAC Ilation (EU) 20	H Article 5	7(f) or Comr	missio	n Delegated					•



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					гауе і	5 of 18
Trade r	name:		BIO-DIFF 1 R			
Produc	t code:	BD1-RTU	Date of compilation:	03.04.2023.	Version:	6
a construction of the second se						
12.7.		erse effects				
	No advers	e effects are expe	cted.			
		osal consideratio				
13.1.	Waste tr	eatment methods	\$			
10.1.1		·				
13.1.1.		/Packaging dispos				_
			isposed of according to the nat aste. Submit for disposal to the l			
		mental and Nature	•	legal person addition.		
	ł					
13.1.2.	Waste co	odes/waste desig	nations according to Law:			
	No infor	mation available				
13.1.3.	Waste co	odes/waste desigi	nations according to Low:			
			contains residual hazardous su	bstances or is conta	minated with h	azardous
<u> </u>	substand	ces				
13.1.4.		disposal – relevar				
	Waste m	ust not be dispos	sed of into the sewage system.			
13.1.5.		sposal recommen				
		•	duct's remains into the sewage y in charge. Do not dispose of tl			
			ectors authorized by the ministr			
	ignition	may occur.			· · ·	
13.1.6.	6. Relevant Community provisions:					
	Disposal	must be made a	ccording to official regulations.			
SECTIO	N 14. Trans	sport informatio	n			
	Transporti	ng/shipment by r	oad (ADR)			
UN num	nber:		1230			
UN prop	per shipping	g name:	Methanol			
Transpo	ort hazard cl	ass(es):	3 (6.1)			
Packing	group:		11			
Environ	mental haza	ards:	-			
Special	precautions	for user:	-			



				Page 1	6 of 18		
Trade name:		BIO-DIFF 1 R	TU REAGENT				
Product code:	BD1-RTU	Date of compilation: 03.04.2023. Version: 6					
_							
· · · · · · · · · · · · · · · · · · ·	ting/shipment by rail (R						
UN number:		1230					
UN proper shippi		Methanol					
Transport hazard	class(es):	3 (6.1)					
Packing group:		II					
Environmental ha	zards:	-					
Special precaution	ns for user:	-					
Transpor	ting/shipment by inland	waterways (ADN)					
UN number:		1230					
UN proper shippi	ng name:	Methanol					
Transport hazard	class(es):	3 (6.1)					
Packing group:		II					
Environmental ha	zards:	-					
Special precaution	ns for user:	-					
Transpor	ting/shipment by sea (II	MDG)					
UN number:		1230					
UN proper shippi	ng name:	Methanol					
Transport hazard	class(es):	3 (6.1)					
Packing group:		II					
Environmental ha	zards:	-					
Special precaution	ns for user:	-					
	according to Annex II and the IBC code:	-					
Transpor	ting/shipment by air (IC	AO-TI/IATA-DGR)					
UN number:		1230					
UN proper shipping name:		Methanol					
Transport hazard class(es):		3 (6.1)					
Packing group:		I					
Environmental ha	zards:	-					
Special precaution	ns for user:	-					
Further informatio	on: -						

SECTIC	DN 15. Regulatory information
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations



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Trade name:	BIO-DIFF 1 RTU REAGENT				
Product code:	BD1-RTU	Date of compilation:	03.04.2023.	Version:	6

	Authorisations and/or res	strictions on use
	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	<ul> <li>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 793/9 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;</li> <li>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2000 on the limitation of emissions of volatile organic compounds due to the use of organi solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 98/24/EC of 7 April 1998 on the protection of the health and safet of workers from the risks related to chemical agents at work;</li> <li>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 1 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;</li> <li>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</li> </ul>
	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	

SECTIO	ECTION 16. Other information				
16.1.	Indication of changes:	-			
16.2.	Abbreviations and acronyms:	<ul> <li>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</li> <li>IMDG: International Maritime Code for Dangerous Goods</li> <li>IATA: International Air Transport Association</li> <li>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</li> <li>EINECS: European Inventory of Existing Commercial Chemical Substances</li> <li>CAS: Chemical Abstracts Service (division of the American Chemical Society)</li> <li>DNEL: Derived No-Effect Level (UK REACH)</li> <li>LC50: Lethal concentration, 50 percent</li> <li>LD50: Lethal dose, 50 percent</li> <li>PBT: Persistent, Bioaccumulative and Toxic</li> <li>vPvB: very Persistent and very Bioaccumulative</li> </ul>			



-

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

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Trade name:	BIO-DIFF 1 RTU REAGENT				
Product code:	BD1-RTU	Date of compilation:	03.04.2023.	Version:	6

16.3.	-	literature references source of data:	-
16.4.		sification and procedure 2/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)
Classifie	catior		Classification procedure
_			-
16.5.	Rele	evant H statements (num	ber and full text)
		225	Highly flammable liquid and vapor.
	H:	301+311+331	Toxic if swallowed, in contact with skin or if inhaled.
		370	Causes damage to organs (eyes).
16.6.	Trai	ning advice:	-
16.7.	Furt	her information:	<ul> <li>** "X" in the product code marks different volumes (different packaging of the product)</li> <li>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.</li> </ul>

ANNEX: Exposure scenario resulting to Chemical safety assessment



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Trading name:	BIO-DIFF 2 RTU REAGENT				
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4	

SECTI	ON 1: Identification of	the substan	ce/mixture a	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	BIO-DIFF 2	2 RTU REAGE	NT	
	Chemical name:	-			
	Catalogue number:	BD2-RTU			
1.2.	Relevant identified use	es of the sub	stance or mi	xture and uses advised against	
	Uses:		Buffered I	red component of Bio-Diff RTU kit.	
	Uses advised against:		Only the i	dentified 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:	E	BioGnost Ltd.		
	Address:	٢	Medjugorska 59, Zagreb		
	Telephone number:	-	+385 1 2409997		
	Fax no.: +		+385 1 2404039		
	e-mail of competent p	erson: <u>r</u>	msds@biognost.hr		
	National contact: -		-		
1.4.	Emergency telephone	number			
	National Protection ar	d Rescue Di	rectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards identification			
2.1.	Classification of the substance or	mixture		
2.1.1.	Classification according to Regula	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	l text of Hazard- and EU Hazard-sta	itements: see S	ection 16	
2.2.	Label elements			
	Product identification:	BIO-DIFF 2 R	TU REAGENT	
	Identification number: -			
	Authorization no.: -			
	Hazard pictograms:	-		



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Trading name:		BIO-DIFF 2 RTU REAGENT				
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4		
Signal wo	ord:	_				

	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	Endocrine Disrupting Properties:	
	No known endocrine disrupting prope	erties.

SECTION 3. Co	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	-			

SECTI	ON 4. First aid measures		
4.1.	Description of first aid measured	ures	
	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 ai	der: Treat symptomatically.	
4.2.	Most important symptoms and effects, both acute and delayed		
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.	
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Long- term exposure may cause drying, cracking and tingling sensation of skin.	
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.	



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Trading name: Product code: BD2-RTU Following ingestion:			BIO-DIFF 2 RTU REAGENT					
		BD2-RTU	Date of compilation:	14 November 2022	Version: 4			
		ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mo burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.					
4.3.	Indication	n of any immedia	te medical attention and special	treatment needed				
	-							

SECTIO	ON 5. Firefighting measures	
5.1.	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:	water jet
5.2.	Special hazards arising from the su	bstance or mixture
	Hazardous combustion products:	No information available
5.3.	Advice for firefighters	
	Use a self-contained open-circuit c Cool closed containers exposed to	ompressed air breathing apparatus and fireproof clothing. fire with water spray or vapor.
5.4.	Additional information	
	Remove sources of heat and ignitic Do not contaminate the environme	

SECTIO	ON 6. Accidental release meas	ıres	
6.1.	Personal precautions, protecti	ve 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 (s	ee Section 8).	
6.2.	Environmental precautions:		
	Do not dispose of in sewage, Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National orate (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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					Tuge 4 01 10			
Trading name: Product code: BD2-RTU			BIO-DIFF 2 RTU REAGENT					
		BD2-RTU	Date of compilation:	Version: 4				
6.3.2.	Cleaning	ıp:	Where possible, the substant material (sand, diatomaceor in tightly closed impermeat ventilated storage rooms un persons authorized by the M Protection. After disposal of materials with water.	us earth, vermiculite). Plac ole containers. Store the su ntil disposal. Submit for di Ministry of Environmental	te the waste material ubstance in well isposal to the legal and Nature			
6.3.3.	Other info	ormation:	-					
6.4.	Reference	to other section	S					
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment			quipment.				

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:	Keep away from sources of heat and ignition. Do not smoke.				
	Measures to prevent aerosol and dust generati	ion: 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 incompatibilities					
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, 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)					



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Trading name:		BIO-DIFF 2 R	TU REAGENT	
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4

Recommendations:	-
Industrial sector specific solutions:	-

8.1.	Control para	meters							
Substance			CAS N	lo			exposure limit term values	Biolo	gical limit values
					р	pm	mg/m <sup>3</sup>		5
-			-			-	-	No informa	ation available
	f								
Substa name:	ince -								
EC No	: -		CAS No:	-					
DNEL	· · · · · · · · · · · · · · · · · · ·								
					Indu	ustrial			
Route	of exposure:		cute		Acute		Chror		Chronic
Noute		effe	ct local	effe	ect syste	emic	effect le	ocal	effect systemic
Oral		-		-			-	-	
Inhalat	tion	-		-			-	-	
Derma		-		-			-	-	
Critica	l physical parar	neters: s	olubility, flar	nmabilit	ty, corro	osivity:	-		
					Con	sumer	1		
Route	of exposure:				Acute		Chror		Chronic
	<b>F</b>	effe	ct local	effect sys		emic	effect le	ocal	effect systemic
Oral		-		-			-	-	
Inhalat		-		-			-	-	
Derma		-		-			-		
PNEC									
	nmental protec	tion targ	get			PNEC			
Fresh water				No information available					
Freshwater sediments				No information available					
Marine water				No information available					
Marine sediments			No information available						
Food chain					No information available				
Microo	organisms in se	wage tre	eatment			No infor	mation availab	le	
Soil (a	gricultural)					No information available			



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Trading name:	me: BIO-DIFF 2 RTU REAGENT			
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4

Air			No information available		
8.2.	Exposure controls				
8.2.1.	Appropriate engineering	controls	· · · · · · · · · · · · · · · · · · ·		
	Substance/mixture relate measures to prevent exp 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 prevent exposure:	revent	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 pr exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.		
8.2.2.	Personal protection equi	pment			
8.2.2.1.	Eye and face protection:	on: Safety glasses that stick to face (preventing splashing) (EN visor.			
8.2.2.2.	Skin protection				
			tive 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		
	()ther skin protection.		ear antistatic clothing made of natural fibers (such as cotton) with long eves (EN 13034), and shoes that cover the entire foot (EN 10335).		
8.2.2.3.	Respiratory protection:	filter f	tive 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 relate measures to prevent exp		See Section 6		
	Structural measures to preserve exposure:	revent	Use modern equipment.		
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.		
	Technical measures to pr exposure:	event	See Section 6		



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Trading name: BIO-DIFF 2 RTU REAGENT		TU REAGENT		
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4

	Value	Method
Physical state:	liquid	No information available
Color:	red	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
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:	5.5 – 6.5	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
Other information		

SECTIC	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.					

# **SECTION 11. Toxicological information**



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Trading name:	BIO-DIFF 2 RTU REAGENT						
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4			

	city:				
Route of exposure:	Method		Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure t	ime Results
Oral exposure:	No information available	-	LD <sub>50</sub>	_	-
Dermal exposure:	No information available	-	LD <sub>50</sub>	-	-
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-	-
Specific ta	rget organ toxicity – si	ngle exposure (S	TOT SE):		
	Specifi	c effects	Target	organ	Note
Oral exposure:	No information a	available	No informatio	on available	-
Dermal exposure:	No information a	available	No information available		-
Inhalation exposure	No information a	available	No information available		-
Aspiration	hazard:	No inform	nation available		
·					
Irritation a	nd corrosion:				
	Exposure time	Species	Evaluation	Method	Note
	-	rabbit	-		
Skin irritation:					
Skin irritation: Eye irritation:	-	rabbit	-		
	-	rabbit	-		
		rabbit	-		
Eye irritation:			-		
Eye irritation: Sensitizatio	on	able	-		
Eye irritation: Sensitizatio Dermal exposure: Inhalation exposure:	on No information avail	able			
Eye irritation: Sensitizatio Dermal exposure: Inhalation exposure:	on No information avail No information avail related to the physica Swallowing may co	able able I, chemical and to ause irritation of evels of concenti g, aspiration caus	oxicological chara mucosa, tingling ration may cause ses coughing, diffi	cteristics sensation in th nausea, abdon	ninal pain and vomiting



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Trading name:				<b>BIO-DIFF</b>	FF 2 RTU REAGENT				
Product code:	BD2-	RTU	Date o	of compilatio	n: 14 Novem	ber 2022	Version: 4		
Inhalation exposi	lire <sup>.</sup>		large amount eezing, heada	•	inadequately ve ea.	ntilated perime	eter may cause		
Eye exposure:		rect eye co nsation.	ntact may cau	ise slight to m	noderate irritatio	n, lacrimation a	nd burning		
Repeate	ed dose to	oxicity (sub	acute, subchro	onic, chronic)					
<b></b>		ose	Exposure time	Species	Method	Evaluation	Note		
Subacute oral	No inf availabl	ormation e	No information available	No information available	No information available	No informatio available	n -		
Subacute dermal	No inf availabl	ormation e	No information available	No informatior available	No information available	No informatio available	n -		
Subacute inhalation	No information available		No information available	No informatior available	No information available	No informatio available	n -		
Subchronic oral	No inf availabl	ormation e	No information available	No information available	No information available	No informatio available	n -		
Subchronic dermal	No inf availabl	ormation e	No information available	No information available	No information available	No informatio available	n -		
Subchronic inhalation	No inf availabl	ormation e	No information available	No informatior available	No information available	No informatio available	n -		
Chronic oral	No inf availabl	ormation e	No information available	No informatior available	No information available	No informatio available	n -		
Chronic dermal	No inf availabl	ormation e	No information available	No informatior available	No information available	No informatio available	n -		
Chronic inhalation	No inf availabl	ormation e	No information available	No information available	No information available	No informatio available	n -		
Specific	target or	gan toxicit	y – repeated e	exposure (STC	DT RE):				
			pecific effects	•	Target or	rgan	Note		
Subacute oral	۱		tion available		No information available -		-		
Subacute dermal	1	No informa	tion available	٨	lo information av	/ailable	-		
Subacute inhalat	ion N	No informa	tion available	Ν	lo information a	vailable	-		



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Trading name:			BIC	BIO-DIFF 2 RTU REAGENT						
Product of	code:	BD2-RTU	Date of com	Date of compilation: 14 November 2022						
Subchroni	ic oral	No informa	tion available	No ii	nformation available	-				
Subchroni	ic dermal	No informa	tion available	No ii	nformation available	-				
Subchronic inhalation No information			tion available	No ii	nformation available	-				
Chronic o	ral	No informa	tion available	No ii	nformation available	-				
Chronic dermal No information		tion available	No ii	nformation available	-					
Chronic inhalation No informatio		tion available	No ii	nformation available	-					
C	CMR effec	ts (carcinogenicity	/; mutagenicity; repr	oductive to	oxicity)					
C	Carcinoge	nicity:	Current studies	on test an	imals did not indicate car	cinogenic effe	ects.			
Mutagenicity <i>in-vitro</i> :			Current in vitr	o tests di	d not indicate mutagenic	effects.				
G	Genotoxic	ity:		No information available						
Ν	Autagenio	city <i>in-vivo</i> :	Current in viv	Current in vivo tests did not indicate mutagenic effects.						
G	Germ cell	mutagenicity:	No information	No information available						
R	Reproduct	tive toxicity:	No toxicity or organs.	No toxicity on reproductive organs was determined in reproductive organs.						
3	summary	of evaluation of th	ne CMR properties:	-						
11.2. lı	nformatic	on on other hazard	ds:							
11.2.1. E	ndocrine	disrupting prope	rties:							
٩	No known	endocrine disrup	ting properties that	affect hum	an health.					
11.2.2.	Other info	ormation:								
-										

SECTION 12. Ecological information								
12.1. Toxicity								
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	-	-		
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	-	-		
Algae/aquatic plants	IC <sub>50</sub>	8 days	No information available	No information available	-	-		
Microorganisms	LC <sub>50</sub>	72 hours	-	-	-	-		
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		



Value

Species

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

Trading nam						рті		1	Page 11		
Trading nam				D-+-	BIO-DIFF 2	I		- 2022	Versior		
Product cod	e:	BD2-RTU	Date of compilation:				14 November 2022			n: 4	
Fish LC <sub>50</sub>		LC <sub>50</sub>	96 hou	ırs			information ilable	No information available		-	
Crustacea: EC		EC <sub>50</sub>	48 hou	ırs	No information available		information ilable	No informatio available	n -		
Algae/aquatio	: plants	IC <sub>50</sub>	72 hou	ırs	No information available	No information available		No informatio available	n -		
Other organis	sms	-	-		-	-		-	-		
		and degrada	bility								
Abio		radation	LC 12				-			N1 /	
	Degradation half-liv		It-lives	es Method			Evaluation			Note	
Marine water	No ir	No information available			information availa	No information available			-		
Fresh water	No ir	nformation av	ailable	No	information availa	able	No information available -			-	
Air	No ir	nformation av	ailable	No	information availa	able	No informa	tion availab	le	-	
Soil	No ir	nformation av	vailable	No	information availa	able	No informa	tion availab	le	-	
Biod	egrada	tion									
% Degradation	on	Time (day	s)		Method		Evaluation		Not	е	
No informatic available		o infor vailable	mation	on No information available			o informatior vailable	n No ir avail	nformatic able	on	
12.3. Bioa	ccumula	ative potentia	al								
Octa	nol-wa	ter partition o	oefficien	t (log	Kow)						
Value	Conc	centration	рН	°C	Method		Evaluat	ion	No	ote	
-	No i availab	information lle	-	-	No informatio available	on	No informa available	tion _			
Bioco	oncentr	ation factor (	BCF)								
Value					Mathad		Evoluation		No		

Method

Evaluation

Note



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Tradin	ng name:		BIO-DIFF 2 RTU REAGENT									
Produ	ct code:	BD2-	RTU	D	ate of co	ompil	ation:	14 No	vember 2	022	Vers	sion: 4
No information No inform available available		inform ble	ation No information available		No information available			No information available				
	Chronic	ocotovici										
Chronic ecotoxicity Value Dos		Dose		osure ime	Spe	ecies	Met	hod	Eva	luation	Note	
Chronic toxicity on fish LC		LC <sub>50</sub>	No	mation	No infori availa	mation able	No inform availab	ation i	No nform availal	nation ble	-	
Chronic toxicity on crustacea ( <i>Daphnia</i> )		EC <sub>50</sub>	No infor availa	mation able	No infori availa	mation able	No inform availab	ation i	No nform availal	nation ble	-	
12.4.			ed distributi vailable	on in e	environme	ental o	compart	ments:				
	Surface	tension:										
	Valu	e	°C	C	oncentrat	tion		Metho	d		Ν	ote
	No informa available		o formation ⁄ailable	No information No inf available availal		formation - ble		-				
	Adsorpt	ion / des	orption									
Transp		A/D coe Henry's d	efficient	lo	og Kow	E١	vaporati	on rate	Met	hod		Note
Soil-wa	ater Ava	i ailable	nformation	No ir availa	nformatio able		o inform ailable	nation	No infor available		n _	
Water-	-air No ava	i ailable	nformation	No ir availa	nformatio able		o inform ailable	nation	No infor available		n _	
Soil-air	r No ava	i ailable	nformation	No ir availa	nformatio able		o inform ailable	nation No information available		n _		
12.5.			d vPvB asses	ssment								
	No into	rmation a	vailable									



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Trading name:	BIO-DIFF 2 RTU REAGENT						
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12.6.	Endocrine disrupting propertie	es
	No known endocrine disruptir	ng properties that affect the environment.
12.7.	Other adverse effects	
	No adverse effects are expect	ed.
SECTIO	N 13. Disposal considerations	5
13.1.	Waste treatment methods	
13.1.1.	Product/Packaging disposal	:
	Submit for disposal to the le Protection.	egal person authorized by the Ministry of Environmental and Nature
13.1.2.	Waste codes/waste designa	tions according to Law:
	No information available	
13.1.3.	Waste treatment – relevant	information:
	No information available	
	1	
13.1.4.	Sewage disposal – relevant i	information:
	Waste must not be disposed	d of into the sewage system.
13.1.5.	Other disposal recommenda	ations:
	authorized by the ministry ir	act'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 ors authorized by the ministry in charge. Do not dispose of in places where
13.1.6.	Relevant Community provisi	ions:
	-	
SECTIO	N 14. Transport information	
	Transporting/shipment by roa	
UN num		Not subject to transport regulations.
	per shipping name:	-
Transpo	ort hazard class(es):	-



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Trading name:	BIO-DIFF 2 RTU REAGENT					
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4		
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Transporti	ng/shipment by rail	(RID)				
UN number:		Not subject to transport	regulations.			
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:		Not subject to transport	regulations.			
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:		Not subject to transport	regulations.			
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-TI/IATA-DGR)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	g name:	-				
Transport hazard cl	ass(es):	-				
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Further information	: The product	is not subject to classificatio	n.			



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Trading name:	BIO-DIFF 2 RTU REAGENT						
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4			

15.1.	<ul> <li>Safety, health and environmental regulations/legislation specific for the substance or mixture</li> <li>EU regulations</li> <li>Authorization and/or restrictions of use</li> </ul>		
	Authorizations:	-	
	Restrictions:	-	
	Other EU regulations:	<ul> <li>Regulation (EC) No 1907/2006 of the European Parliament and of the Council or 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;</li> <li>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;</li> <li>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;</li> <li>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;</li> <li>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</li> </ul>	
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC- 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		
	None		

SECTION 16. Other information				
16.1.	Indication of changes:	-		
		PBT	Stable, bioaccumulative and toxic	
		vPvB	Strongly stable and strongly bioaccumulative.	
16.2.	Abbreviations and acronyms:	LD <sub>50</sub>	Lethal dose, 50%	
		LC <sub>50</sub>	Lethal concentration, 50%	
		STOT-SE	Specific target organ toxicity - single exposure	
16.3.	Key literature references and source of data:	-		



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Trading name:	BIO-DIFF 2 RTU REAGENT				
Product code:	BD2-RTU Date of compilation: 14 November 2022 Version:				

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 (number 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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Trading name:	<b>BIO-DIFF 3 RTU REAGENT</b>				
Product code:	BD3-RTU	Date of compilation:	14 November 2022	Version: 6	

	CTION 1: Identification of the substance/mixture and of the company/undertaking				
1.1.	Product identifier				
	Trading name:	BIO-DIFF 3	RTU REAGE	NT	
	Chemical name:	-	- BD3-RTU		
	Catalogue number:	BD3-RTU			
1.2. Relevant identified uses of the substance or mixture and uses advised against			xture and uses advised against		
	Uses:		Buffered l	blue component of Bio-Diff RTU kit.	
	Uses advised against:	Uses advised against:		identified uses are advised.	
	Reason why uses advis	sed against:	device, re	ct is intended for use only as an <i>in vitro</i> diagnostic medical istered at the Agency for Medicinal Products and Medical d 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: Bi		BioGnost Ltd.		
	Address: N		Medjugorska 59, Zagreb		
	Telephone number: +		+385 1 2409997		
	Fax no.: +		+385 1 2404039		
	e-mail of competent person:		msds@biognost.hr		
	National contact: -		-		
1.4.	Emergency telephone number				
	National Protection and Rescue Dire		ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTION 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 category code:		Hazard statements*:	
	Not identified as hazardous substance.		-	
2.1.2.	Additional information			
	-			
*For ful	*For full text of Hazard- and EU Hazard-statements: see Section 16			
2.2.	Label elements			
	Product identification:	BIO-DIFF 3 R	TU REAGENT	
	Identification number:	-		
	Authorization no.:	-		
	Hazard pictograms:	-		


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Trading name:		<b>BIO-DIFF 3 RTU REAGENT</b>	
Product code:	BD3-RTU	Date of compilation: 14 November 2022	Version: 6
Signal wo	rd:	-	
Signal wo	rd:	-	

	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	Endocrine Disrupting Properties:	
	No known endocrine disrupting prop	erties.

SECTION 3. Co	omposition/inform	ation on ingredients	5	
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	-

SECTI	ON 4. First aid measures			
4.1.	Description of first aid measu	ıres		
	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 ai	Treat symptomatically.		
4.2.	Most important symptoms a	nd effects, both acute and delayed		
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.		
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.		
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.		



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Tradin	g name:		BIO-DIFF 3 RTU REAGENT							
Product code: B		BD3-RTU	Date of compilation:	14 November 2022	Version:	6				
Following ingestion:		g ingestion:	Swallowing may cause irritat burning sensation; higher lev abdominal pain and vomitin coughing, difficult breathing suffocation.	vels of concentration may g. In case of vomiting, asp	cause nausea	I, S				
4.3.	Indication	n of any immedia	te medical attention and special	treatment needed						
-										

SECTIO	ON 5. Firefighting measures	
5.1.	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:	water jet
5.2.	Special hazards arising from the su	bstance or mixture
	Hazardous combustion products:	No information available
5.3.	Advice for firefighters	
	Use a self-contained open-circuit c Cool closed containers exposed to	compressed air breathing apparatus and fireproof clothing. fire with water spray or vapor.
5.4.	Additional information	
	Remove sources of heat and ignitic Do not contaminate the environme	

SECTIO	ON 6. Accidental release meas	ures				
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           Mathematical prevention methods:         members without protective equipment. Remove a sparks and ignition. Do not smoke.						
	Mark the area using proper signs.					
6.1.2.	For emergency responders:	For emergency responders:				
	Wear protective equipment (s	ee Section 8).				
6.2.	Environmental precautions:					
	Do not dispose of in sewage, Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National prate (NPRD) on 112.				
6.3.	Methods and material for cor	tainment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.				



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					Tuge 4 01	10			
Tradin	ig name:		BIO-DIFF 3 RTU REAGENT						
Produ	ct code:	BD3-RTU	Date of compilation:	14 November 2022	Version:	6			
6.3.2.	Cleaning	nb:	Where possible, the substant material (sand, diatomaceo in tightly closed impermeal ventilated storage rooms up persons authorized by the I Protection. After disposal of materials with water.	us earth, vermiculite). Plac ble containers. Store the su ntil disposal. Submit for di Ministry of Environmental	te the waste m ubstance in we sposal to the and Nature	naterial ell legal			
6.3.3.	Other info	ormation:	-						
6.4.	See Section 7 for information								
			ion about secure handling. ion about personal protective eq	quipment.					

See Section 13 for information about containment.

SECTIO	DN 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 generati	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 incompatibilities					
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat 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)					



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Recommendations:	-
Industrial sector specific solutions:	-

			ols/personal	protec					
8.1. C	ontrol para	meters			Occurs	ational	avpocure limit		
۲.	ubstance		CAS N	lo			exposure limit term values	Biological lin	nit values
Substance			10	pp		mg/m <sup>3</sup>	Diological III	int values	
-		_		-	-	-	No information ava	ailable	
								I	
Substance name:	-								
EC No: -			CAS No:	-					
DNEL	1		I	1			<u> </u>		
					Indu	strial			
Devite of a		A	Acute		Acute		Chron	ic (	Chronic
Route of exposure: ef		effe	ect local	effe	ect syste	mic	effect lo	ocal effe	ct systemic
Oral -		-		-			-	-	
Inhalation -		-		-		-		-	
Dermal		-		-	-		-	-	
Critical phy	ysical parar	neters: s	olubility, flar	nmabilit	ty, corro	sivity:	-		
					Cons	umer	1		
Route of e	xposure.				Acute		Chron		Chronic
	Aposure.	effe	ect local	l effect sys		mic	effect lo	ocal effe	ct systemic
Oral		-		-			-	-	
Inhalation		-		-			-	-	
Dermal		-		-		-		-	
PNEC									
	ental protec	tion tar	get			PNEC			
Fresh wate						No information available			
Freshwater sediments				No information available					
Marine water				No information available					
Marine sec	diments				1	No infor	mation availabl	e	
Food chair	ו				1	No information available			
Microorga	nisms in se	wage tr	eatment		١	No infor	mation availabl	e	
Soil (agricu	ultural)				٦	No information available			



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Trading name:	BIO-DIFF 3 RTU REAGENT								
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Air			No information available						
8.2.	Exposure controls								
8.2.1.	Appropriate engineering	controls	S						
	Substance/mixture relate measures to prevent exp 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:	revent	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 pr exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.						
8.2.2.	Personal protection equi	oment							
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								
	Hand protection:		ective gloves must be according to the EU Directive 2016/425/EEC and lard EN 374. Glove material: nitrile rubber						
			Glove thickness: ≥0.50 mm						
			Break through time: >480 min						
	Other skin protection:		ar antistatic clothing made of natural fibers (such as cotton) with long eves (EN 13034), and shoes that cover the entire foot (EN 10335).						
8.2.2.3.	Respiratory protection:	filter f	ective full face mask (EN 136) or half mask (EN 140) equipped with a for organic vapors, type "A" (boiling point >65°C) acording to EN 7) used when concentration levels exceed GVI.						
8.2.2.4.	Thermal hazards:	No inf	formation available						
8.2.3.	Environmental exposure	controls	S						
	Substance/mixture relate measures to prevent exp		See Section 6						
	Structural measures to pr exposure:	revent	Use modern equipment.						
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.						
	Technical measures to pr exposure:	event	See Section 6						



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Trading name:	BIO-DIFF 3 RTU REAGENT							
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Melting point , Boiling point of and boiling ran Flammability: Lower and upp Flash point: Auto-ignition t Decomposition pH: Kinematic visco Solubility: Partition coeffi (log value): Vapour pressu		Value	Method		
Odour/odour toMelting point ofBoiling point ofand boiling ranFlammability:Lower and uppFlash point:Auto-ignition toDecompositionpH:Kinematic viscoSolubility:Partition coeffic(log value):Vapour pressu	cal state:	liquid	No information available		
Melting point , Boiling point of and boiling ran Flammability: Lower and upp Flash point: Auto-ignition t Decomposition pH: Kinematic visco Solubility: Partition coeffi (log value): Vapour pressu		blue	No information available		
Boiling point of and boiling rarFlammability:Lower and uppFlash point:Auto-ignition tDecompositionpH:Kinematic viscoSolubility:Partition coeffi(log value):Vapour pressu	r/odour threshold:	no odor/no information available	No information available		
and boiling ranFlammability:Lower and uppFlash point:Auto-ignition tDecompositionpH:Kinematic viscoSolubility:Partition coeffi(log value):Vapour pressu	ng point / freezing point:	No information available	No information available		
Lower and upp Flash point: Auto-ignition t Decomposition pH: Kinematic visco Solubility: Partition coeffi (log value): Vapour pressu	g point or initial boiling point oiling range:	No information available	No information available		
Flash point: Auto-ignition t Decomposition pH: Kinematic visco Solubility: Partition coeffi (log value): Vapour pressu	nability:	No information available	No information available No information available		
Auto-ignition tDecompositionpH:Kinematic viscoSolubility:Partition coeffi(log value):Vapour pressu	r and upper explosion limit:	No information available			
Decomposition pH: Kinematic visco Solubility: Partition coeffi (log value): Vapour pressu	point:	No information available	No information available		
pH: Kinematic visco Solubility: Partition coeffi (log value): Vapour pressu	ignition temperature:	No information available	No information available		
Kinematic visco Solubility: Partition coeffi (log value): Vapour pressu	mposition temperature:	No information available	No information available		
Solubility: Partition coeffi (log value): Vapour pressu		6.3 – 7.3	No information available		
Partition coeffi (log value): Vapour pressu	natic viscosity:	No information available	No information available		
(log value): Vapour pressu	ility:	No information available	No information available		
	on coefficient n-octanol/water alue):	No information available	No information available		
	ur pressure:	No information available	No information available		
Density and/or	ty and/or relative density	No information available	No information available		
Relative vapou	ve vapour density:	No information available	No information available		
Particle charac	le characteristics:	No information available	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.							

# **SECTION 11. Toxicological information**



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Trading name:		BIO-DIFF 3 R	TU REAGENT		
Product code:	BD3-RTU	Date of compilation:	14 November 2022	Version:	6

<b>.</b>	n on hazard classes as								
Acute toxic	city:				1				
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure t	ime Re	esults			
Oral exposure:	No information available	-	LD <sub>50</sub>	-		-			
Dermal exposure:	No information available	-	LD <sub>50</sub>	-		-			
Inhalation exposure:	No information available	-	LC <sub>50</sub>						
Specific tar	get organ toxicity – sir	nale exposure (S	TOT SF):						
opecne ta	<u>, , , , , , , , , , , , , , , , , , , </u>	c effects	-	organ	Not	e			
Oral exposure:	No information a			No information available -					
Dermal exposure:	No information a		No informatio		-				
Inhalation exposure			No informatio		-				
· · · · · ·									
Aspiration	hazard:	No inform	nation available						
Irritation a	nd corrosion:								
	Exposure time	Species	Evaluation	Method	Note				
Skin irritation:	-	rabbit	_						
Eye irritation:	_	rabbit	_						
,	1								
Sensitizatio	on								
Dermal exposure:	No information availa	able							
Inhalation exposure:	No information availa	able							
Symptoms	related to the physical	l, chemical and to	oxicological chara	cteristics					
Oral exposure:	Swallowing may ca sensation; higher l In case of vomiting concentration may	evels of concenti g, aspiration caus	ration may cause ses coughing, diffi	nausea, abdon	ninal pain and	vomiting			
	concentration may cause suffocation. Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.								



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Trading name:				BIO-DIFF 3 RTU REAGENT							
Product code:	BD3-F	RTU	Date o	f compilatio	n: 14 Novem	ber 2022	Version: 6				
Inhalation exposi	lire <sup>.</sup>		large amount: eezing, heada	•	inadequately ve ea.	entilated perime	eter may cause				
Eye exposure:		ect eye co Isation.	ntact may cau	se slight to m	noderate irritatio	n, lacrimation a	and burning				
Repeate	ed dose to	xicity (sub	acute, subchro	onic, chronic)							
· · ·	Do	se	Exposure time	Species	Method	Evaluation	Note				
Subacute oral	No info available		No information available	No information available	No information available	No informatio available	n -				
Subacute dermal	No infc available		No information available	No information available	No information available	No informatic available	n -				
Subacute inhalation	No info available		No information available	No information available	No information available	No informatio available	n -				
Subchronic oral	No info available		No information available	No information available	No information available	No informatio available	n -				
Subchronic dermal	No info available		No information available	No information available	No information available	information informatio					
Subchronic inhalation	No info available		No information available	No information available	No information available	No informatio available	n -				
Chronic oral	No info available		No information available	No information available	No information available	No informatio available	n -				
Chronic dermal	No info available		No information available	No information available	No information available	No informatio available	n -				
Chronic No information inhalation available		No information available	No information available	No information available	No informatio available	on -					
Specific	target org	an toxicit	y – repeated e	xposure (STC	DT RE):						
- 1	<u> </u>		pecific effects	,	Target o	rgan	Note				
Subacute oral	N	o informa	tion available	N	lo information a	vailable	-				
Subacute dermal	N	o informa	tion available	Ν	lo information a	vailable	-				
Subacute inhalat	ion N	o informa	tion available	Ν	lo information a	vailable	-				



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Product code:BD3-RTUDate of compilation:14 November 2022Version:6Subchroit oralNo information available </th <th>Trading name:</th> <th></th> <th colspan="10">BIO-DIFF 3 RTU REAGENT</th>	Trading name:		BIO-DIFF 3 RTU REAGENT									
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 dermal       No information available       No information available       -         Chronic inhalation       No information available       No information available       -         Chronic inhalation       No information available       No information available       -         Chronic inhalation       No information available       No information available       -         CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)       -       -         Carcinogenicity:       Current studies on test animals did not indicate carcinogenic effects.         Mutagenicity <i>in-vitro</i> :       Current <i>in vitro</i> tests did not indicate mutagenic effects.         Genotoxicity:       No information available       -         Mutagenicity <i>in-vivo</i> :       Current <i>in vivo</i> tests did not indicate mutagenic effects.	Product code:	BC	03-RTU	Date of com	pilation: 14 Novemb	er 2022	Version:	6				
Subchronic inhalationNo information availableNo information available-Chronic oralNo information availableNo information available-Chronic dermalNo information availableNo information available-Chronic dermalNo information availableNo information available-Chronic dermalNo information availableNo information available-Chronic inhalationNo information availableNo information available-Chronic inhalationNo information availableChronic inhalationNo information information availableChronic information information information information information availableCarcinogenicity: in-vitro:Current in vitro test animals did not indicate mutagenic effectsMutagenicity in-vitro:No information availableMutagenicity in-vitro:Current in vitro test did not indicate mutagenic effectsMutagenicity in-vitro:Current in vitro test did not indicate mutagenic effects	Subchronic oral		No informa	tion available	No information ava	ilable	-					
Chronic oralNo information availableNo information available-Chronic dermalNo information availableNo information available-Chronic inhalationNo information availableNo information available-No information availableNo information availableCMR effects (carcinogenicity; reproductive toxicity)Current studies on test animals did not indicate carcinogenic effectsMutagenicity <i>in-vitro</i> :Current <i>in vitro</i> tests did not indicate mutagenic effectsMutagenicity <i>in-vivo</i> :Current <i>in vivo</i> tests did not indicate mutagenic effects.	Subchronic derr	nal	No informa	tion available	No information ava	ilable	-					
Chronic dermal       No information available       No information available       -         Chronic inhalation       No information available       No information available       -         CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)       -       -         Carcinogenicity:       Current studies on test animals did not indicate carcinogenic effects.       -         Mutagenicity <i>in-vitro</i> :       Current <i>in vitro</i> tests did not indicate mutagenic effects.       -         Mutagenicity <i>in-vitro</i> :       Current <i>in vivo</i> tests did not indicate mutagenic effects.       -         Mutagenicity <i>in-vivo</i> :       Current <i>in vivo</i> tests did not indicate mutagenic effects.       -	Subchronic inha	lation	No informa	tion available	No information ava	ilable	-					
Chronic inhalation       No information available       No information available       -         CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)       -       -         Carcinogenicity:       Current studies on test animals did not indicate carcinogenic effects.       -         Mutagenicity <i>in-vitro</i> :       Current <i>in vitro</i> tests did not indicate mutagenic effects.       -         Genotoxicity:       No information available       -         Mutagenicity <i>in-vivo</i> :       Current <i>in vivo</i> tests did not indicate mutagenic effects.	Chronic oral No information			tion available	No information ava	ilable	-					
CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)Carcinogenicity:Current studies on test animals did not indicate carcinogenic effects.Mutagenicity <i>in-vitro</i> :Current <i>in vitro</i> tests did not indicate mutagenic effects.Genotoxicity:No information availableMutagenicity <i>in-vivo</i> :Current <i>in vivo</i> tests did not indicate mutagenic effects.	Chronic dermal No informatio			tion available	No information ava	ilable	-					
Carcinogenicity:       Current studies on test animals did not indicate carcinogenic effects.         Mutagenicity in-vitro:       Current in vitro tests did not indicate mutagenic effects.         Genotoxicity:       No information available         Mutagenicity in-vivo:       Current in vivo tests did not indicate mutagenic effects.	Chronic inhalati	on	No informa	tion available	No information ava	-						
	Mutag Genoto Mutag Germ o	enicity <i>i</i> enicity: enicity <i>i</i> ell mut	in-vitro: in-vivo: agenicity:	Current <i>in vitr</i> No information Current <i>in vivo</i> No information No toxicity or	Current <i>in vitro</i> tests did not indicate mutagenic effects. No information available Current <i>in vivo</i> tests did not indicate mutagenic effects. No information available No toxicity on reproductive organs was determined in reproductive							
11.2. Information on other hazards:					· · · ·							
11.2.1. Endocrine disrupting properties:				ting properties that	affect human health.							
11.2.1.       Endocrine disrupting properties:         No known endocrine disrupting properties that affect human health.	11.2.2. Other i	nforma	tion:									
11.2.1. Endocrine disrupting properties:	-											

SECTION 12. Ecologi	SECTION 12. Ecological information										
12.1. Toxicity											
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note					
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	-	-					
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	-	-					
Algae/aquatic plants	IC <sub>50</sub>	8 days	No information available	No information available	-	-					
Microorganisms	LC <sub>50</sub>	72 hours	-	-	-	-					
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note					



Trading name:	•				BIO-DIFF 3	RTU	REAGENT					
Product code:	E	3D3-RTU		Date	of compilation:	14	4 Novembei	2022	Versio	n: 6		
Fish LC <sub>50</sub> S		96 hours				information ilable	No informatio available	n -				
Crustacea:	Crustacea: EC <sub>50</sub> 48		48 hours		No information available		information ilable	No informatio available				
Algae/aquatic p	lants	IC <sub>50</sub>	72 hou	rc	No information available		No information available No available available		o information informa			
Other organism	IS	-	-		_	-		-	-			
12.2. Persiste	0000	and degradal	aility									
		adation	Jinty									
		gradation ha	f-lives		Method		E۱	aluation		Note		
Marine water		formation av		No i	information availa	able	No informa		e	-		
Fresh water	No information available			No i	information availa	able	No informa	tion availabl	e	-		
Air	No information available			No i	information availa	able	No informa	tion availabl	e	-		
Soil	No information available			Noi	information availa	able	No informa	tion availabl	e	-		
Biodeg	iradati	ion										
% Degradation		Time (day	s)		Method		Evaluation		No	te		
No information available	Nc	o information N		No information					No information available			
12.3. Bioaccu	umula	itive potentia	I									
Octano	ol-wat	er partition o	oefficien	t (log	Kow)							
Value		entration	рН	°C	Method		Evaluat		N	ote		
- N a\	o information - vailable		- No information available		on	No information available						
	t-			<u>.</u>	1		i 					
	centra	ation factor (	-				Free lose at					
Value		Speci	52		Method		Evaluatior	I	No	ne		



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Tradin	g name:		BIO-DIFF 3 RTU REAGENT									
Produ	ct code:	BD3-	RTU	D	ate of c	ompil	ation:	14 November 2022		Version: 6		
No info availab	ormation le	No availal	inform ole			No information available			No information available			
	Chronic e	cotoxicit	tv.									
Value Dose			Exposure time		Spe	ecies	Met	hod	Eva	luation	Note	
Chronic toxicity on fish LC <sub>50</sub>			information ir		-	lo No nformation inform vailable availab		ation i	No nforr availa	nation ble	-	
Chronic toxicity on crustacea ( <i>Daphnia</i> )		information		No inforr availa	mation Ible	No inform availab	ation i	No nforr Ivaila	nation ble	-		
12.4.	Mobility Known o		ed distributi	on in e	environm	ental c	compart	ments:				
	No inforr	nation av	ion available									
	Surface to	ension:	sion:									
	Value		°C	Concentration		Method Iformation able			Ν	lote		
	NoNoinformationinformationavailableavailable							No inf availat	-			
	Adsorptio	on / desc	orption									
Transpo	ort	A/D coet lenry's c		lc	og Kow	E١	vaporati	on rate	Metl	hod		Note
Soil-wa	ater No avai	ir lable	nformation	No ir availa	nformatio able		o inform ailable	nation	No informatic available		on -	
Water-	air No avai	ir lable	nformation	No ir availa	nformatio able		o inform ailable	nation	No inforr available		on -	
Soil-air	. No avai	ir lable	nformation	No ir availa	nformatio able		o inform ailable	nation	No information available		on -	
40		(										
12.5.			d vPvB asses	sment								
	No information available											



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Trading name:	BIO-DIFF 3 RTU REAGENT					
Product code:	BD3-RTU	Date of compilation:	14 November 2022	Version: 6		

12.6.	Endocrine disrupting properties				
	No known endocrine disrupting prope	rties that affect the environment.			
12.7.	Other adverse effects				
	No adverse effects are expected.				
SECTIO	N 13. Disposal considerations				
13.1.	Waste treatment methods				
13.1.1.	Product/Packaging disposal:				
	Submit for disposal to the legal pers Protection.	on authorized by the Ministry of Environmental and Nature			
13.1.2.	Waste codes/waste designations acc	ording to Law:			
	No information available				
13.1.3.	Waste treatment – relevant information:				
	No information available				
13.1.4.	Sewage disposal – relevant informat				
	Waste must not be disposed of into	the sewage system.			
13.1.5.	Other disposal recommendations:				
	authorized by the ministry in charge	ains into the sewage system. Submit the remains to the collectors Do not dispose of the packaging into the sewage system. Submit orized by the ministry in charge. Do not dispose of in places where			
13.1.6.	Relevant Community provisions:				
	-				
SECTIO	ON 14. Transport information				
	Transporting/shipment by road (ADR)				
UN num		subject to transport regulations.			
	oper shipping name: -				
Transpo	ort hazard class(es): -				



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Trading name:	BIO-DIFF 3 RTU REAGENT					
Product code:	BD3-RTU	Date of compilation:	14 November 2022	Version:	6	
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions for user:		-				
Transporti	ng/shipment by ra	ail (RID)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	g name:	-				
Transport hazard cl	ass(es):	-				
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Inland wat	erway transport (A	ADN)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	g name:	-				
Transport hazard cl	ass(es):	-				
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Transporti	ng/shipment by s	ea (IMDG)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	g name:	-				
Transport hazard cl	ass(es):	-				
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Transporti	ng/shipment by a	ir (ICAO-TI/IATA-DGR)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	g name:	-				
Transport hazard cl	ass(es):	-				
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	s for user:	-				
Further informatior	: The produ	ict is not subject to classificatio	on.			



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Trading name:	BIO-DIFF 3 RTU REAGENT						
Product code:	BD3-RTU	Date of compilation:	14 November 2022	Version: 6			

	EU regulations	
	Authorization and/or res	trictions of use
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<ul> <li>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;</li> <li>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 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;</li> <li>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;</li> <li>REACH Restrictions on the manufacturing, placing on the market and use of certair dangerous substances, mixtures and articles (Annex XVII);</li> </ul>
	Information according 19 guideline)	099/13/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	
	None	

SECTIO	SECTION 16. Other information				
16.1.	Indication of changes:	-			
		PBT	Stable, bioaccumulative and toxic		
		vPvB	Strongly stable and strongly bioaccumulative.		
16.2.	Abbreviations and acronyms:	LD <sub>50</sub>	Lethal dose, 50%		
		LC <sub>50</sub>	Lethal concentration, 50%		
		STOT-SE	Specific target organ toxicity - single exposure		
16.3.	Key literature references and source of data:	-			



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Trading name:	BIO-DIFF 3 RTU REAGENT					
Product code:	BD3-RTU	Date of compilation:	14 November 2022	Version: 6		

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 (number and full text)				
	H: -	-			
16.6.	Training advice:	-			
		** "X" in the product code marks different volumes (different packagings of the product)			
16.7.					

ANNEX: Exposure scenario resulting to Chemical safety assessment



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Trading name:	BUFFER SOLUTION, pH 6.8					
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4	

<b>SECT</b>		ON 1: Identification of the substance/mixture and of the company/undertaking Product identifier				
	Trading name:	BUFFER SO	LUTION, p	oH 6.8		
	Chemical name:	-	- ·			
	Catalogue number:	PUF68-OT-	X**			
1.2	Relevant identified use	Relevant identified uses of the substance or		nixture and uses advised against		
	Uses:	Uses:		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:	Address:		Medjugorska 59, Zagreb		
	Telephone number:	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	SECTION 2. Hazards identification				
2.1	Classification of the substance	or mixture			
2.1.1	Classification according to Reg	ulation (EC) No 1	272/2008 (CLP)		
	Hazard class and catego	ory code:	Hazard statements*:		
	Not identified as hazardous sul	ostance.	-		
2.1.2.	Additional information				
	-				
*For ful	l text of Hazard- and EU Hazard-	statements: see S	SECTION 16		
2.2	Label elements				
	Product identification:	BUFFER SOLUTI	ON, pH 6.8		
	Identification number:	-			
	Authorization number:	-			
	Hazard pictograms:	-			



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Trading name:	BUFFER SOLUTION, pH 6.8					
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4	

	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 assessment</b> : According to the results of its assessment, this substance is not a PBT or a vPvB.					

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

SECT	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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Trading name:		BUFFER SOLUTION, pH 6.8						
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4			
	·							

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

SECTIO	SECTION 5. Firefighting measures						
5.1	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						
	Do not contaminate the environm	ent with extinguishing media.					

SECTIO	ON 6. Accidental release measure	ures					
6.1	Personal precautions, protective	e equipment and emergency procedures					
6.1.1.	For non-emergency personnel						
	Protective equipment:	Use personal protective equipment (see Section 8).					
	Accident prevention methods:	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, o Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National rate (NPRD) on 112.					
6.3	Methods and material for cont	ainment 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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Trading name:	BUFFER SOLUTION, pH 6.8								
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4				

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.         Conditions for safe storage, including any incompatibilities         Keep in tightly closed and upright set containers in						
7.2	Conditions for safe storage, including any incompatibilities						
	Technical measures and storage conditions:	well ventil	Keep in tightly closed and upright set containers in a well ventilated storage roomsat temperatures ranging from 15 to 25 °C.				
	Packaging materials:	Manufactu	anufacturer's original packaging.				
	Requirements for storage rooms and vessels:		ep away from food and drink. Keep the containers htly 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:	and do no	ace the unused material in the storage room it use empty containers for storing other Do not store with incompatible materials on 10).				
7.3	Specific end use(s)	·					
	Recommendations:	-					
	Industrial sector specific solutions:	-					

SECTION 8. Exposure controls/personal protection									
8.1 Control parameters	Control parameters								
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values					
		ppm mg/m <sup>3</sup>							



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Trading nam	e:				BL	JFFER SC	DLUTIO	N, pH 6.8			
Product code	e: l	PUF68-0	OT-X**		Date c	of compil	ation:	22 Dec 2	022	Version:	4
	i			:			1			ī	
-				-		-		-		-	
Substance nar	me:	-					1				
EC No:		-	CAS No	: -							
DNEL											
					In	dustrial			1		
Route of		Acu			ute		Chro			Chronic	
exposure:		effect	local	effect s	systemio	c	effect	local		effect systemic	
Oral	-			-		-			-		
Inhalation	-			-		-			-		
Dermal	-			-		-			-		
Critical physic	al parar	meters: s	olubility,	flammab			-				
		1				nsumer			1		
Route of exposure:		Acute Acute effect local effect system			Chronic		Chronic				
exposure:		effec	,		systemi	ic effect local			effect systemic		
Oral		-		-		-			-		
Inhalation		-		-		-			-		
Dermal		-		-		-			-		
PNEC	1		4			PNEC					
Environmenta	i protec	ction targ	get			No information available					
Fresh water											
Freshwater see	aiment	5				No information available No information available					
Marine water Marine sedime											
Food chain	ents					No information available No information available					
Microorganisr	me in ce	waaa tr	ootmont								
		ewaye in	eatment			No information available					
Soil (agricultu Air	[d])					No information available No information available					
All							mation	avallable			
8.2 E	xposure	e control	s								
	•		ineering	controls							
S	ubstan	ce/mixtu	ire related e during i	d measure			e equip			oms. Use persona ink or smoke in th	



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Trading name:		BUFFER SOLUTION, pH 6.8								
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4					

	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 low 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:	Protect	ctive 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:		adequate ventilation to the premises where the product is 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	ction 6	
	Structural measures to prevent exposure:	Use mo	odern equipment.	
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.	
	Technical measures to prevent exposure:	See Section 6		

SECT	SECTION 9. Physical and chemical properties				
9.1	Information on basic physical and chemical properties				
		Value	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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Trading name:		BUFFER SOLUTIO	N, pH 6.8		
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

	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:	6.75 – 6.85	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	ON 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

SECTION 11. Toxi	SECTION 11. Toxicological information							
11.1 Informatio	11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008							
Acute toxi	icity:							
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	-			
		·						
Specific ta	arget organ to	xicity – single exposur	e (STOT SE):					



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Trading name:			<b>BUFFER SO</b>	LUTION	, pH 6.8		uge e er r	-
Product code:	PUF68-OT-X**	Da	ate of compila		22 Dec 202	2 ۱	/ersion:	4
i i oddet code.					22 8 6 6 2 6 2	-		
	Spec	ific effects		Target	organ		Note	
Oral:	No information	available	No inf	ormation	available	-		
Dermal:	No information	available	No information available		-			
Inhalation:	No information	available	No inf	ormation	available	-		
Aspiration hazard:		N	lo information a	available.				
Irritatior	and corrosion							
	Exposur	e time	Species	Evaluat	tion Meth	od	Note	
Skin corrosion/irritatic	on:	-		-	-	-		
Serious eye damage/irritatior	- 1	-		-	-	-		
	:	:		1		:		
Sensitiza	ation							
Skin sensitization	: -							
Respiratory sensi	tization: -							
Sympto	ms related to the pl	nysical, chemic	al and toxicolo	gical chai	acteristics			
Oral exposure:	No informati	on available						
Dermal exposure	: No informati	on available						
Inhalation exposu	ure: No informati	on available						
Eye exposure:	No informati	on available						
Repeate	d dose toxicity (sub	acute, subchro	onic, chronic)					
	Dose	Exposure time	Species	Metho	od Eva	luation	Note	
Subacute oral	No information available	No information available	No information available	No inform availal		ormation iilable	-	
Subacute dermal	No information available	No information available	No information available	No inform availal		ormation iilable	-	
Subacute inhalation	No information available	No information available	No information available	No inform availal		ormation iilable	-	



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Trading name:	BUFFER SOLUTION, pH 6.8						
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4		

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 target organ toxicity – repeated exposure (STOT RE):

	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	-

 CIVIL ETIECIS (Carcinogenicity, muta	geniety, reproductive toxicity)
Carcinogenicity:	No information available
Mutagenicity in vitro:	No information available
 Genotoxicity:	No information available
Mutagenicity in vivo:	No information available
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No information available



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Trading name:		N, pH 6.8			
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

	Summary of evaluation of the CMR No information available			
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 information:			
	-			

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	-	_	_	-	_	-



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Trading name:		BUFFER SOLUTION	, pH 6.8		
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

Abiot	ic degr	adation									
	De	egradation h	alf-lives		Ν	lethod		Evaluatio	n		Note
Marine water	No i	nformation	available	-			No information available		-		
Fresh water	No information available			info ailab	ormation le	No i avail	nformatio able	n	-		
Air	No information available			info ailab	ormation le	No ii avail	nformatio able	n	-		
Soil	No information available			info ailab	ormation lle	No ii avail	nformatio able	n	-		
Biode	gradati	ion									
% Degradati	-	Time (	days)		N	lethod		Evaluatio	n		Note
No information		No ir	nformatio		inf	ormation		nformatio			rmation
available		available		ava	ailab	ole	avail	able		available	
		itive potentia er partition o		t (log k	Kow	)					
Value	Conce	entration	рН	°C		Method		Evalu	ation		Note
-	-		-	-		_		-		-	
Віосо	ncentra	ation factor (	(BCF)	2						;	
Value		Speci	es		ľ	Vethod	Evaluation		Note		
No information No information available available			No information available		No information available		on	-			
Chror	nic ecot	oxicity				1			1		
Valu	ie	Do	se E	xposur time	e	Species	N	Method	Evalu	ation	Note
Value Dose ti			Nhecies		No		No				



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Trading name: BUFFER SOLUTION, pH 6.8														
Produc	ct cod	le:	PUF68	3-OT-X**		Date	of co	mpilatio	on:	22 Dec	2022	Versi	on:	4
Chronic toxicity on crustacea ( <i>Daphnia</i> ) EC <sub>50</sub>			information in		No infor availa	mation able	No inform availal		No information available	-				
12.4	N 4 - I-		1											
12.4														
	Known or predicted distribution in environmental compartments:         No information available													
		ace ter		unuble										
		Value		°C	Co	oncentra	tion		Meth	od		No	te	
	NoNoinformationinformationavailableavailable			informat ilable	ion	No inf availat	ormatic ble	on	-					
	Adso	orptior	n / deso	rption								1		
Transpo	ort		./D coef enry's co		log Kow		E١	Evaporation rate		ſ	Method		Note	
Soil-wa	ter	No availa		formation	No information available			No information No inf available available		formation able	-			
Water-a	air	No availa		formation	No information available			No information No info available availabl		formation able	-			
Soil-air		No availa				No information available		No information No information available		formation able	-			
12.5.	Resu	ults of	PBT and	l vPvB asses	sment									
	Base	ed on a	available	e data, the p	roduct	does no	ot cont	tain any	PBT or	vPvB su	bstances.			
12.6.				ng properti				·	•					
	NO P	known	endocr	ine disrupti	ng pro	perties tr	hat aff	ect the e	environi	ment.				
12.7.	Othe	er adve	erse effe	octs										
				are expect	ed.									
SECTIO	N 13.	. Dispo	osal con	sideration	s									
13.1	W	aste tr	eatment	t methods										

<b>T</b>					Page 13 of 1	6			
Trading			BUFFER SOLUTION, pH 6.8						
Produc	t code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4			
13.1.1.	Product/	/Packaging disposal:							
	Submit f Protectio		person authorized by the Mini	istry of Environmen	tal and Nature				
13.1.2.	Waste co	odes/waste designatior	ns according to Law:						
	Packagir	ng that contains residua	al hazardous substances or is co	ontaminated with h	azardous substar	ices			
13.1.3.	Waste tr	reatment – relevant info	prmation:						
	No infor	mation available							
13.1.4.	Sewage	disposal – relevant info	ormation:						
	-	•	into the sewage system.						
	i								
13.1.5.	Other di	sposal recommendatio	ns:						
	authoriz	ed by the ministry in ch	s remains into the sewage syste narge. Do not dispose of the pa authorized by the ministry in c	ckaging into the se					
13.1.6.	Relevant	t Community provision	5:						
13.1.0.									

# SECTION 14 TRANSPORT INFORMATION

o transport regulations
o transport regulations



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F					ragerrori	0		
Trading name:			<b>BUFFER SOLUTIO</b>	N, pH 6.8				
Product code:	PUF68-OT-X**		Date of compilation:	22 Dec 2022	Version:	4		
UN number:		Not	subject to transport regu	lations				
UN proper shipping name:		-						
Transport hazard class(es):		-						
Packing group:		-						
Environmentally hazardous:		-						
Special precautions for user:								
Transport	ting/shipment by sea (IN	MDG)						
UN number:		Not subject to transport regulations						
UN proper shippir	ng name:	-						
Transport hazard o	class(es):	-						
Packing group:		-						
Environmentally h	azardous:	-						
Special precaution	is for user:	-						
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:		-						
Transport	ting/shipment by air (IC	AO-TI	/IATA-DGR)					
UN number:		Not subject to transport regulations						

UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information: -	

SECTIO	SECTION 15. Regulatory information							
15.1	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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Trading name:		BUFFER SOLUTIO	N, pH 6.8		
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

	Other EU regulations:	<ul> <li>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;</li> <li>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;</li> <li>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;</li> <li>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;</li> <li>REACH Restrictions on the manufacturing, placing on the market and use of certain</li> </ul>						
	Information according 1999 guideline)	dangerous substances, mixtures and articles (Annex XVII); Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC- quideline)						
	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 assessmen							
	None							

SECTIO	SECTION 16. Other information				
16.1	Indication of changes:	-			
16.2	Abbreviations and acronyms:	<ul> <li>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</li> <li>IMDG: International Maritime Code for Dangerous Goods</li> <li>IATA: International Air Transport Association</li> <li>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</li> <li>EINECS: European Inventory of Existing Commercial Chemical Substances</li> <li>CAS: Chemical Abstracts Service (division of the American Chemical Society)</li> <li>DNEL: Derived No-Effect Level (UK REACH)</li> <li>LC50: Lethal concentration, 50 percent</li> <li>LD50: Lethal dose, 50 percent</li> <li>PBT: Persistent, Bioaccumulative and Toxic</li> <li>vPvB: very Persistent and very Bioaccumulative</li> </ul>			
16.3.	Key literature references and source of data:	-			



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Trading name:	BUFFER SOLUTION, pH 6.8					
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4	

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 (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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Trading name:		BUFFER SOLUTION	, pH 7.2		
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

1.1	Product identifier	the substance	e/mixture	e and of the company/undertaking		
	Trading name:	BUFFER SO	LUTION, p	н 7.2		
	Chemical name:	-	-			
	Catalogue number:	PUF72-OT-	X**			
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against		
	Uses:	s:		olution for use in hematology, 6 mM.		
	Uses advised against:	Uses advised against:		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:	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	SECTION 2. Hazards identification				
2.1	Classification of the substance	or mixture			
2.1.1	Classification according to Reg	ulation (EC) No 1	272/2008 (CLP)		
	Hazard class and catego	ory code:		Hazard statements*:	
	Not identified as hazardous sub	ostance.	-		
2.1.2.	Additional information				
	-				
*For ful	l text of Hazard- and EU Hazard-	statements: see S	SECTION 16		
2.2	Label elements				
	Product identification:	BUFFER SOLUTI	ON, pH 7.2		
	Identification number:	-			
	Authorization number:	-			
	Hazard pictograms:	-			



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Trading name:		<b>BUFFER SOLUTION</b>	l, pH 7.2		
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

	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 as</b> PBT or a vPvB.	sessment: According to the results of its assessment, this substance is not a

SECTION 3. Cor	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.	-		

SECT	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 effects, 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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Trading name:	BUFFER SOLUTION, pH 7.2						
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4		
· · · · · · · · · · · · · · · · · · ·							

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

SECTIC	SECTION 5. Firefighting measures				
5.1	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				
	Do not contaminate the environm	ent with extinguishing media.			

SECTIO	ON 6. Accidental release measure	ıres		
6.1	Personal precautions, protectiv	e 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 c (see Section 8).	ase of inadequate ventilation use adequate airways protective equipment		
6.2	Environmental precautions:			
	Do not dispose of in sewage, o Protection and Rescue Directo	Irainage system and waterways. In case of large spillage contact National rate (NPRD) on 112.		
6.3	Methods and material for cont	ainment 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:	n: Do not use incompatible materials (see Section 10).		
6.4	Reference to other sections			



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Trading name:	BUFFER SOLUTION, pH 7.2						
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4		

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. The	noroughly wa	sh hands after work and before eating.			
7.2	Conditions for safe storage, including any incompatibilities					
	Technical measures and storage conditions:		ghtly closed and upright set containers in a lated storage roomsat temperatures ranging o 25 °C.			
	Packaging materials:	Manufact	Manufacturer's original packaging.			
	Requirements for storage rooms and vessels:		eep away from food and drink. Keep the containers ghtly closed.			
	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:	and do no	ace the unused material in the storage room ot use empty containers for storing other . Do not store with incompatible materials on 10).			
7.3	Specific end use(s)					
	Recommendations:	-				
	Industrial sector specific solutions:	-				

SECTION 8. Exposure controls/personal protection						
8.1 Control parameters	8.1 Control parameters					
Substance			exposure limit term values	Biological limit values		
		ppm	mg/m³	-		



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Trading na	me:	BUFFER SOLUTION, pH 7.2									
Product co	de:	PUF72-0	OT-X**		Date c	of compilation: 22 Dec 202		022	Version:	4	
	÷			:	I			: 			
-				-		-		-		-	
		1									
Substance n	name:	-									
EC No:		-	CAS No	: -							
DNEL											
				[	In	dustrial					
Route of		Acu			cute		Chro			Chronic	
exposure:		effect	local	effect s	systemi	с	effect	local		effect systemic	
Oral		-		-		-			-		
Inhalation		-		-		-			-		
Dermal		-		-		-			-		
Critical phys	sical para	ameters: s	olubility,	flammab	ility, coi	rrosivity:	-				
				1	Co	nsumer			1		
Route of			cute		cute		Chro			Chronic	
exposure:		effec	t local	effect s	systemi	с	effect	local		effect systemic	
Oral		-		-		-			-		
Inhalation		-		-		-			-		
Dermal		-		-		-			-		
PNEC											
Environmen	tal prote	ection targ	get			PNEC					
Fresh water						No infor					
Freshwater s	sedimen	ts				No infor					
Marine wate	er					No information available					
Marine sedi	ments					No information available					
Food chain						No information available					
Microorgani	isms in s	ewage tre	eatment			No information available					
Soil (agricul	tural)					No information available					
Air			No information available								
8.2	Exposu	re control	s								
8.2.1.	Approp	oriate eng	ineering o	controls							
		nce/mixtu t exposure					e equip			oms. Use persona 'ink or smoke in th	



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Trading name:	BUFFER SOLUTION, pH 7.2					
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4	

	Structural measures to prevent exposure:		In accordance with Section 7.		
	<b>.</b>		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 lower 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:	Protect	tive 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:		adequate ventilation to the premises where the product is 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	ction 6		
	Structural measures to prevent exposure:	Use mo	odern equipment.		
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.		
	Technical measures to prevent exposure:	See Section 6			

SECTION 9. Physical and chemical properties						
9.1	Information on basic physical and chemical properties					
		Value	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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Trading name:	BUFFER SOLUTION, pH 7.2					
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4	

	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:	7.2	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:	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			

SECTION 11. Toxicological information											
11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008											
Acute to:	Acute toxicity:										
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	-						
Specific t	arget organ to	xicity – single exposur	e (STOT SE):								



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Trading name:			BUFFER SOLUTION, pH 7.2							
Product code:	PUF72-OT-X**	Da	ate of comp	ilation:	22 De	c 2022	Vers	sion:	4	
	1									
	Spec	ific effects	Target organ				Note			
Oral:	No information	available	No	informatio	n availab	le -				
Dermal:	No information	available	No	informatio	n availab	le -				
Inhalation:	No information	available	No	informatio	n availab	le -				
Aspiratio	on hazard:	Ν	lo informatio	on available	9.					
Irritatior	n and corrosion						1			
	Exposur	e time	Species	Evalu	ation	Method		Note		
Skin	_	_		_	-		_			
corrosion/irritatio	on:									
Serious eye damage/irritatior	-	-		-	-		-			
damage/initation	•									
Sensitiza	ation									
Skin sensitizatior	: -									
Respiratory sensi	tization: -									
	:									
Sympto	ms related to the pl	nysical, chemic	al and toxicc	ological cha	aracterist	ics				
Oral exposure:	No informat	on available								
Dermal exposure	: No informat	on available								
Inhalation expos	ure: No informat	on available								
Eye exposure:	No informat	on available								
Repeate	d dose toxicity (sub	acute, subchro	onic, chronic)	)						
	Dose	Exposure time	Species	Meth	nod	Evaluatio	on	Note		
Subacute oral	No information available	No information available	No informatio available	No n infor avail	mation able	No informat available		-		
Subacute dermal	No information available	No information available	No informatio available	n infor avail	mation able	No informat available		-		
Subacute inhalation	No information available	No information available	No informatio available	No n infor avail	mation able	No informat available		-		



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Trading name:		BUFFER SOLUTION, pH 7.2								
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4					

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 target organ toxicity – repeated exposure (STOT RE):

	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	-

enni en eeus (eur en e gement), mata	
Carcinogenicity:	No information available
 Mutagenicity in vitro:	No information available
Genotoxicity:	No information available
Mutagenicity in vivo:	No information available
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No information available



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Trading name:		BUFFER SOLUTION, pH 7.2								
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4					

	Summary of evaluation of the CMR No information available
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 information:
	-

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	information information	
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 No information information available available		-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-



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Trading name:		BUFFER SOLUTION	l, pH 7.2		
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

Abiot	tic degr	adation							
	D	egradation hal	f-lives	١	Method	Evaluatio	n		Note
Marine water	No	information ava	ailable	No information available		No information available		-	
Fresh water	No	No information available			ormation ole	No information available	n	-	
Air	No information available			No inf availal	ormation ole	No information available	n	-	
Soil	No	information ava	ailable	No inf availal	ormation ole	No information available	n	-	
Biode	egradat	ion							
% Degradat	-	Time (da	vs)	N	Vethod	Evaluatio	n		Note
No informatio		No info	ormation	No inf	formation	No information	n		rmation
available		available		availal	bie	available		availabl	e
12.3 Bioac	cumula	ative potential							
Octai	nol-wat	er partition coe	efficient (	log Kow	<i>ı</i> )				
Value	Conc	entration	рН	°C	Method	Evalu	ation		Note
-	-	-				-		-	
Bioco	oncentra	ation factor (BC	CF)						
Value		Species			Method	Evaluati	on		Note
No informatio available			rmation	No information available		No information available		-	
Chro	nic eco	toxicity							
	10	Dose		osure ime	Species	Method	Evalu	ation	Note
Valu	Chronic toxicity on fish		L L						



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Trading name: BUFFER SOLUTION, pH 7.2													
Produc	ct cod	le:	PUF72	2-OT-X**		Date	of co	mpilatio	on:	22 Dec	2022	Version:	4
Chronic crustac		-	)	EC <sub>50</sub>	information in		No infor availa	mation able	on information i		No information available	-	
12.4	.4 Mobility in soil												
				d distributi	on in ei	nvironme	ental o	compart	ments:				
			ation av	ailable									
		ace ter	nsion:										
		/alue		°C	Со	ncentrat	ion		Metho	bd		Note	
	NoNoinformationinformationavailableavailable		ormation		nformati lable	ion	No inf availat	ormatio ole	n	-			
	Adso	orptior	n / deso	rption									
A/D coefficient Transport Henry's constant				log Kow		Ev	Evaporation rate		٢	Method	Note	ć	
Soil-wa	iter	No availa		formation	No information available			o inform vailable			formation ble	-	
Water-a	air	No availa		formation	No in availal	formatio ole		o inform vailable	nation	ion No information available		-	
Soil-air		No availa		formation	No information available			o inform ⁄ailable	information No informati ilable available			-	
12.5.				l vPvB asses									
	Base	ed on a	ivailable	e data, the p	oroduct	does no	t con	tain any	PBT or v	/PvB su	bstances.		
12.6.	End	ocrine	disrupți	ing properti	<u>م</u>								
12.0.			•	ine disrupti		erties th	at aff	ect the e	nvironn	nent			
			chaoch				acan						
12.7.	Othe	er adve	erse effe	ects									
				s are expect	ed.								
				F									
SECTIO	DN 13.	Dispo	osal con	sideration	s								
13.1				t methods									



Inland waterway transport (ADN)

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

Page 13 of 16 Trading name: **BUFFER SOLUTION, pH 7.2** Product code: Date of compilation: Version: 4 PUF72-OT-X\*\* 22 Dec 2022 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: Packaging that contains residual hazardous substances or is contaminated with hazardous substances 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. **Relevant Community provisions:** 13.1.6. \_ SECTION 14 TRANSPORT INFORMATION 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 (RID) UN number: Not subject to transport regulations UN proper shipping name: \_ Transport hazard class(es): \_ Packing group: \_ Environmentally hazardous: \_ Special precautions for user: \_



Special precautions for user:

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

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					Fage 14 01 1	0		
Trading name:			BUFFER SOLUTION, pH 7.2					
Product code:	PUF72-OT-X**		Date of compilation:	22 Dec 2022	Version:	4		
	:		1					
UN number:		No	t subject to transport regu	lations				
UN proper shipping	g name:	-						
Transport hazard cl	lass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	s for user:	-						
Transporti	ng/shipment by sea (II	ИDG	)					
UN number:		Not subject to transport regulations						
UN proper shipping	g name:	-						
Transport hazard class(es):		-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	s for user:	-						
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:		-						
Transporting/shipment by air (IC		AO-1	ΓΙ/IATA-DGR)					
UN number:		Not subject to transport regulations						
UN proper shipping name:		-						
Transport hazard class(es):		-						
Packing group:		-						
Environmentally hazardous:		-						

Further information:	-

-

SECTIO	SECTION 15. Regulatory information			
15.1	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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Trading name:		BUFFER SOLUTIO	N, pH 7.2		
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

	Other EU regulations:	<ul> <li>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;</li> <li>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;</li> <li>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;</li> <li>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;</li> <li>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</li> </ul>
	Information according 199 guideline)	9/13/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 assessment	
	None	

SECTIO	SECTION 16. Other information				
16.1	Indication of changes:	-			
16.2	Abbreviations and acronyms:	<ul> <li>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</li> <li>IMDG: International Maritime Code for Dangerous Goods</li> <li>IATA: International Air Transport Association</li> <li>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</li> <li>EINECS: European Inventory of Existing Commercial Chemical Substances</li> <li>CAS: Chemical Abstracts Service (division of the American Chemical Society)</li> <li>DNEL: Derived No-Effect Level (UK REACH)</li> <li>LC50: Lethal concentration, 50 percent</li> <li>LD50: Lethal dose, 50 percent</li> <li>PBT: Persistent, Bioaccumulative and Toxic</li> <li>vPvB: very Persistent and very Bioaccumulative</li> </ul>			
16.3.	Key literature references and source of data:	-			



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Trading name:	BUFFER SOLUTION, pH 7.2				
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

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 (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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