

#### **BIO-DIFF KIT**

The kit contains:

Bio-Diff 1 reagent

Bio-Diff 2 reagent

Bio-Diff 3 reagent

Buffer tablet pH 6.8

Buffer tablet pH 7.2



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

1.1.	Product identifier			
	Trade name:	BIO-DIFF 1 RE	AGENT	
	Chemical name:	-		
	Catalogue number:	BD1-OT-X**		
1.2.	Relevant identified uses of the	substance or mix	ture and uses advised against	
	Uses:	Fixative agent, component of Bio-Diff kit.		
	Uses advised against:	Only the identified uses are advised.		
	Reason why uses advised against:	device, registe	s intended for use only as an <i>in vitro</i> diagnostic medical ered at the Agency for Medicinal Products and Medical nere 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	ost.hr	
	National contact:			
1.4.	Emergency telephone numbers			
	National Protection and Rescue	Directorate:	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 Regulation (EC) No 1272/2008 (CLP)					
	Hazard class and category code:	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	or full text of Hazard- and EU Hazard-statements: see SECTION 16					
2.2.	Label elements					



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	Product identification:	BIO-DIFF 1 REAGENT	
	Identification number:	-	
	Authorisation number:	-	
	Hazard pictograms:	GHS08	
	Signal word:	Danger	
	Hazard statements:	H225 Highly flammable liquid and vapor. H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled. H370 Causes damage to organs (eyes).	
	Precautionary statements:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves, protective clothing, eye protection, face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.	
	Supplemetal hazard information (EU):	-	
2.3.	Other hazards		
	Endocrine Disrupting Properties:  No known endocrine disrupting properties  Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.		



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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			

4.1.	Description of first aid m	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 least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.			
	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
	-

SECTI	SECTION 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-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.				
5.4.	Additional information				
	Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the 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				
	Protective equipment:		Use personal protective equipment (see Section 8).		
	Accident prevention m	ethods:	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.		Mark the area using proper signs.		
6.1.2.	For emergency respon	ders:			
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).				
6.2.	Environmental precaut	ions:			
	Do not let product ent	er drains. Risk	of explosion.		
6.3.	Methods and materials for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:  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 material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.				
6.3.3.	Other information:	Do not use tools that may cause sparks.				
6.4.	Reference to other se	ections				
	See Section 7 for information on safe handling.					
	See Section 8 for information on personal protective equipment.					
	See Section 13 for dis	sposal information.				

SECTIO	ON 7. Handling and storage		
7.1.	Precautions for safe handling		
7.1.1.	Protection 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	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. Thore	oughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompa	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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	Further information on storage conditions:				ns:	and chen	not place the un do not use emp nicals. Do not so Section 10).	oty contai	ners for stori	ng other
7.3.	Specific er	nd use(s)								
	Recomme	ndations:			-					
	Industrial sector specific solutions: -									
SECTIO	N 8. Expos	ure contr	ols/person	al protec	tion					
8.1.	Control pa	arameters								
	Substance		CAS	No			exposure limit term values	Bi	ological limit	values
				ppm		mg/m³				
Methanol 67-56		6-1	1 200		260	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*), end-of-shift urinary excretion		ne*),		
* For al	•	taining cre	eatinine lev	els, creati	nine conce	ntrati	on < 0.5 g/l and	d > 3.0 g/	'l may not be	taken into
Substa	nce: -			-						
EC No:	-		CAS No:	-						
DNEL										
		1		1	Industi	rial	T			
Route			Acute		Acute .		Chroni			ronic
exposu	ıre:	effe	ect local	ette	ect systemi	С	effect lo	cal	effect	systemic
Oral		260	/ 3	260	-, 1:3		- 2		-	
Inhalati	ion	260 m (metha	_	260 mg (metha	-	, j			260 mg/m <sup>3</sup>	(methanol)
Dermal		-		40 mg/	/kg (metha	nol)			40 mg/kg (	methanol)
Critical	physical par	rameters:	solubility, fl	ammabili	ty, corrosiv	vity:		-		
					Consur	ner	1			
Route of Acute		6.5	Acute		Chronic			ronic		
		ect systemi		effect lo	cal		systemic			
Oral		-	. 2		g (methan	ol)	-		8 mg/kg (n	nethanol)
Inhalati	ion	50 mg (metha		50 mg/m <sup>3</sup> (methanol)			50 mg/m <sup>3</sup> (methanol)		50 mg/m <sup>3</sup> (methanol)	
Dermal		-		8 mg/k	kg (methan	ol)			8 mg/kg (n	nethanol)
PNEC		1								



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Environmental protection target			PNEC		
Fresh wat	er		154 mg/l (methanol)		
Freshwate	er sediments		570.4 mg/kg (methanol)		
Marine water			15.4 mg/l (methanol)		
Marine se	diments		No information available		
Food chai	n		No information available		
Microorga	anisms in sewage treatment		100 mg/l (methanol)		
Soil (agric	cultural)		23.5 mg/kg (methanol)		
Air			No information available		
8.2.	Exposure controls				
8.2.1.	Appropriate engineering measures				
	Substance/mixture related measures to prevent exposure during identified uses:	prot	the product in well ventilated rooms. Use personal ective equipment. Do not eat, drink or smoke in the kspace.		
	Structural measures to prevent exposure:	No i	nformation available		
	Organisational measures to prevent exposure:		anization of work in order to reduce other worker's ence 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:	prot	e shield and safety glasses. Use equipment for eye ection tested and approved under appropriate government dards such as EN 166(EU).		
8.2.2.2.	Skin protection:				
		spec EN3	protective gloves to be used must comply with the cification of EC Directive 2016/425 and the related standard 74.  contact: Glove material: butyl rubber		
	Hand protection:		Glove thickness: 0.70 mm  Break through time: > 480 min  sh contact:  Gloves material: viton (R)  Glove thickness: 0.70 mm  Break through time: > 120 min		



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	Other skin protection:	Complete antistatic suit protecting against chemicals (EN 13688). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Required when vapours/aerosols are generated. Recommended filter type: gas filter AX, colour code brown (EN 371). The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment. Do not let product enter drains. Risk of explosion.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

9.1.	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
	рН:	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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	Partition coefficient n- octanol/water (log value):	No information available	No information available
	Vapour pressure:	128 hPa (20 °C)	No information available
	Density and/or relative density	0.79 (20 °C)	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
	Ignition temperature: 455 °C		

SECTION	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. To	oxicological information	l								
11.1. Inform	ation on hazard classes as	defined in Regul	ation (EC) No 1272	/2008						
Acute toxicity:										
Route of exposure:	Method	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)					



Trade name:

# 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	· I KEAG	EIN I	
Product code:	BD1-OT-X**	Date of o	compilation:	03.0	04.2023.	Version: 6
Inhalation:	No information available	n ra	t	LC <sub>50</sub>	4 h	3.88 mg/l (methanol)
Specific	target organ toxicit	y - single expo	sure (STOT-SE)	:		
; •		fic effects	-	Target	organ	Note
Oral:	No information a		No ir		n available	-
Dermal:	No information av	ailable	No ir	nformation	n available	-
Inhalation:						mixture causes damage to organs
Aspiration	on hazard:	No	o information a	available		
 	and corrosion					
irritation	Exposure	time Sr	pecies Eva	aluation	Method	Note
Skin corrosion/irritatio	_	-	-		-	drying-out effect resulting in rough and chapped skin
Serious eye damage/irritatior	- 1	-	-		-	irritations of mucous membranes
Sensitiza	ation					
Skin sensitization		se sensitizatio	n.			
Respiratory sensitization:	No informati					
Symptoi	ns related to the ph	ysical, chemica	al and toxicolog	gical chara	acteristics:	
Oral exposure:		el irritation, ac	idosis, drop in	blood pre	ssure, feeling	g unwell, vomiting, strong kidney, cardiac.
Dermal exposure:	Minimum level of possibility of dela		J . J	ed exposur	re may cause	absorption and greater
Inhalation exposure:	Airways irritation a drowsiness, heada	·	-	_	•	or concentration, dizzine
Eye exposure:		indness, irreve	rsible damage			s, lesser possibility of lisual impairments may
Donocto	d doso tovicity (c) b	acuto cubebra	nic chronic			
кереате	d dose toxicity (sub			. A	latha -	Typhystics 81.
_	Dose	Exposure time	e Species	IVI	lethod	Evaluation Not



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Trade name:		BIO-DIFF 1 R	EAGENT		
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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	-

C 'C' '		(CTOT DE)
Spacific target organ	1 tavicity – randatac	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	-



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	CMR effects (carcinogenicity, mutagenicity, re	productive 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
	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 houi	rc i	information ilable	No inforr availa	mation able	No inform availal		-	
Algae/aquat plants:	ic	IC <sub>50</sub>	72 houi	rc	information ilable		No information available		nation ole	-	
Other organ	isms	-	-	-		-		-		-	
12.2. Per	sistenc	e and degrada	hility								
		gradation	iomey								
		Degradation h	alf-lives		Method			Eval	luation		Note
Marine wate		information a			information avai	lable	No in	formati	on ava	ilable	-
Fresh water	No	information a	vailable	No	information avai	lable	No in	formati	on ava	ilable	-
Air	No	information a	vailable	No	information avai	lable	No in	No information available -			-
Soil	No	information a	vailable	No	information avai	lable	No in	formati	on ava	ilable	-
	degrad					0 0 0 0					
% Degrada	ition	Time (da	ays)		Method		valuatio			No	te
-		-		-		No in availa	formation ble	on	_		
12.3. Bio	accumi	ulative potenti	al								
Oct	anol-w	ater partition	coefficie	ent (log K	ow)						
Value	Coı	ncentration	рН	°C	Method		Evalua	ntion		N	ote
-	No availa	information able	-	-	-		o inform ailable	ation	-		
Bio	concen	tration Factor	(BCF)								
Value		Spec	ies		Method		Evaluatio	on		No	te
No informat available	ion	No informati available	on							No information available	



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TTOdde	ct code:	BD1-C	71 X	Date of	COM	mation.	05.0	4.2023.	Vei	sion:	6	
	Chronic	· cotovicity										
	Value	ecotoxicity	Dose	Exposure time	Species		Me	Method E		Evaluation		Note
Chronic	onic toxicity on fish LC <sub>50</sub>		LC <sub>50</sub>	No information available		o formation ⁄ailable	No inform availal		No infor			-
Chronic toxicity on crustacea (Daphnia)		EC <sub>50</sub>	No information available	1	o formation vailable	No inform availal		No infor			-	
12.4.	Mobility	in soil										
	Known o	r predicte	d distributi	on in enviro	nmen	tal compartr	ments:					
	No inforr	nation av	ailable									
	Surface t	ension:										
	Val	ue	(	°C		Concentrati	ion		Metho	d		Not
	No information No i available		nformation	Mo information available			No information available			е	-	
	Adsorption	on / desoi A/D coeff										
Transpo	ort	Henry's co		log Ko	W	Evaporatio	on rate Method			Note		
Soil-Wa	ater No avai	in <sup>.</sup> lable	formation	No inform available	ation	No informavailable	ation	No infor		-	-	
Water-A	Air No avai	in <sup>.</sup> lable	formation	No inform available	ation	No informavailable	ation	No infor		-		
Soil-Air	Soil-Air No information available		formation	No inform available	ation	No informavailable	ation	No infor		-		
12.5	Danilla	f DDT and	vPvB asse									
12.5.				o(es) not me	ot the	critoria for	DRT or vi	Dv.R				
12.6.			ng propert	<u> </u>	et tile	criteria ioi	ו אוטוטוטו	۷υ				
12.0.			<u> </u>	not contain (	compo	nents consi	dered to	have en	docrine di	srupting	g pro	perties
	according	g to REAC	H Article 5	7(f) or Comr levels of 0.19	nissio:	n Delegated						•



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12.7.	Other adverse effects		
	No adverse effects are expect	ed.	
SECTIO	N 13. Disposal consideration	s	
13.1.	Waste treatment methods		
13.1.1.	Product/Packaging disposa	:	
	· ·	posed of according to the national and local rules and regulations. Do not e. Submit for disposal to the legal person authorized by the Ministry of Protection.	
12.1.2	W		
13.1.2.	Waste codes/waste designa	tions according to Law:	
	No information available		
13.1.3.	Waste codes/waste designa	tions according to Low:	
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances		
13.1.4.	Sewage disposal – relevant	information:	
	Waste must not be disposed of into the sewage system.		
13.1.5.	Other disposal recommend	ations:	
	authorized by the ministry i	uct'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 cors authorized by the ministry in charge. Do not dispose of in places where	
13.1.6.	Relevant Community provis	ions:	
	Disposal must be made acc	ording to official regulations.	
SECTIO	N 14. Transport information		
	Transporting/shipment by roa	ad (ADR)	
UN number:		1230	
UN proper shipping name:		Methanol	
Transpo	rt hazard class(es):	3 (6.1)	
Packing		II .	
Environr	mental hazards:	-	
Special p	precautions for user:	-	



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Transporting/shipment by rail (R	D)
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland	waterways (ADN)
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IN	MDG)
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-
Transporting/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:	II
Environmental hazards:	-
Special precautions for user:	-
Further information: -	

SECTION 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 REAGENT				
Product code:	BD1-OT-X**	Date of compilation:	03.04.2023.	Version:	6

	Authorisations and/or res	unctions on use
	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation an 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/EE and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 200 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 amendin Directive 1999/13/EC; Council 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; 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 mixture amending and repealing Directives 67/548/EEC and 1999/45/EC, and amendin Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
5.2.	Chemical safety assessme	nt
	None	

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



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Trade name:	BIO-DIFF 1 REAGENT				
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16.3.		literature references source of data:	-
16.4.	Classification and procedure used to 0 1272/2008 (CLP)		used to derive the classification for mixture according to Regulation (EC)
Classific	cation	1	Classification procedure
_			-
16.5.	. Relevant 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:	-
			** "X" in the product code marks different volumes (different packaging of the product)
16.7.	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.

ANNEY E
ANNEX: Exposure scenario resulting to Chemical safety assessment
<del>-</del>



#### **SAFETY DATA SHEET** BIOGNOST® According to Regulation (EC) No. 1907/2006

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

SECTION	ON 1: Identification of	the substan	ce/mixture a	and of the company/undertaking
1.1.	Product identifier			
	Trading name:	BIO-DIFF 2	2 REAGENT	
	Chemical name:	-		
	Catalogue number:	BD2-OT-X	BD2-OT-X**	
1.2.	Relevant identified us	es of the sub	of the substance or mixture and uses advised against	
	Uses:		Buffered r	red component of Bio-Diff kit.
	Uses advised against:		Only the i	dentified uses are advised.
	Reason why uses advi	lvised against: device, registered at the Agency for Medic		uct is intended for use only as an <i>in vitro</i> diagnostic medical gistered at the Agency for Medicinal Products and Medical nd there is no reason to use it for other purposes
1.3.	Details of the supplier	of the safety	y data sheet	
	Supplier:	E	BioGnost Ltd.	
	Address:	ſ	Medjugorska 59, Zagreb +385 1 2409997 +385 1 2404039 msds@biognost.hr	
	Telephone number:	-		
	Fax no.:	-		
	e-mail of competent p	person: <u>r</u>		
	National contact:	-	•	
1.4.	Emergency telephone	number		
	National Protection a	nd 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 Regulation (EC) No 1272/2008 (CLP)			
	Hazard class and category	/ code:	Hazard statements*:	
	Not identified as hazardous substance		-	
2.1.2.	Additional information			
	-			
*For fu	ll text of Hazard- and EU Hazard-sta	atements: see S	Section 16	
2.2.	Label elements			
	Product identification:	BIO-DIFF 2 R	EAGENT	
	Identification number:	-		
	Authorization no.:	-		
	Hazard pictograms:	-		



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Trading name:		BIO-DIFF 2 REAGENT				
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Signal v	vord:					
Hazard	statements:	-				
Precaut	ionary statements:	-				
Sunnler	metal hazard information					

### 2.3. Other hazards Endocrine Disrupting Properties:

(EU):

No known endocrine disrupting properties.

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	-

SECTION	CTION 4. First aid measures				
4.1.	Description of first aid meas	ures			
	Following inhalation: Following skin contact:		-		
			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.		
			Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.		
	Following eye contact:	i	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.		
	Following ingestion:		Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.		
	Self-protection of the first aider:		Treat symptomatically.		
4.2.	Most important symptoms a	nd effe	cts, both acute and delayed		
	Following inhalation:		tion of large amounts of vapors in inadequately ventilated perimeter ause coughing, sneezing, headache and nausea.		
	Following skin contact:	_	irritation. After short exposure, resorption effects are not likely. Long- exposure may cause drying, cracking and tingling sensation of skin.		
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation burning sensation.			



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Trading name:	BIO-DIFF 2 REAGENT			
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	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, 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 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: water jet		
5.2.	Special hazards arising from the substance or mixture		
	Hazardous combustion products: No information available		
5.3.	Advice for firefighters		
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.  Cool closed containers exposed to fire with water spray or vapor.		
5.4.	Additional information		
	Remove sources of heat and ignition.		
	Do not contaminate the environment with extinguishing media.		

SECTIO	ON 6. Accidental release measu	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 and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.	
	Emergency procedures:	Mark the area using proper signs.	
6.1.2.	For emergency responders:		
	Wear protective equipment (see Section 8).		
6.2.	Environmental precautions:		
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.		
6.3.	Methods and material for containment and cleaning up		
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.	



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

6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other section	ns
	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:	Keep away from sources of heat and ignition. Do no smoke.		
	Measures to prevent aerosol and dust generat	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 wel 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)			



Soil (agricultural)

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Trading name:				BIO-DI	FF 2 R	EAGENT			
Product code:	BD2-O	Г-Х**	Date	of compilatio	n: 14	Novem	nber 2022	Version:	4
Recomme	ndations:								
		cific solution	ns:	_					
SECTION 8. Expos	ure contr	ols/persona	al protec	tion					
8.1. Control pa									
Substance		CAS I	No	Occupationa values/sho			Biolog	gical limit valu	ıes
				ppm	m	g/m³	]		
-	-			-		-	No informa	tion available	
Substance - name:									
EC No: -		CAS No:	-						
DNEL			·						
				Industrial					
Route of exposure:	,	Acute	Acute			Chronic		Chroni	С
Route of exposure.	effe	ect local	effect systemic			effect local		effect syst	emic
Oral	-		-		-		-		
Inhalation	-		-		-		-		
Dermal	-		-				-		
Critical physical par	ameters:	solubility, fla	mmabili	ty, corrosivity:		-			
			1	Consumer	_				
Route of exposure:		Acute	Acute			Chronic		Chroni	
	effe	ect local	effe	ect systemic		effect lo	ocal	effect syst	emic
Oral	-		-		-		-		
Inhalation	-		-		-		-		
Dermal	-		-		-		-		
PNEC				DNIEG					
Environmental protection target				PNEC					
Fresh water				No information available					
Freshwater sediments				No information available					
				No information available  No information available					
	COMOGO +	oatmont							
Marine water  Marine sediments  Food chain  Microorganisms in		reatment		No info	ormation ormation	n availab	le le		

No information available



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Trading name:	BIO-DIFF 2 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 expeduring identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.				
	Structural measures to prexposure:	revent	No information available				
	Organisational measures to prevent exposure:  Technical measures to prevent		Organization of work in order to reduce other worker's influence during work process.				
			Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.				
8.2.2.	Personal protection equip	oment					
8.2.2.1.	Eye and face protection:		Safety glasses that stick to face (preventing splashing) (EN 166) or visor.				
8.2.2.2.	Skin protection						
			ective gloves must be according to the EU Directive 2016/425/EEC and dard EN 374.				
	Hand protection:		Glove material: nitrile rubber				
			Glove thickness: ≥0.50 mm  Break through time: >480 min				
	Other skin protection:		r antistatic clothing made of natural fibers (such as cotton) with long es (EN 13034), and shoes that cover the entire foot (EN 10335).				
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) acording to EN 14387) used when concentration levels exceed GVI.					
8.2.2.4.	Thermal hazards:	No inf	formation available				
8.2.3.	Environmental exposure	controls					
	Substance/mixture related measures to prevent exposure:		See Section 6				
Structural measures to exposure:		event	Use modern equipment.				
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.				
	Technical measures to preexposure:	event	See Section 6				

#### **SECTION 9. Physical and chemical properties**



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Trading name:	BIO-DIFF 2 REAGENT					
Product code:	BD2-OT-X**	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
рН:	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

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**



#### SAFETY DATA SHEET

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

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Acute toxic			llation (EC) No 123		
Route of exposure: Method		Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure ti	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 tar	get organ toxicity – sir	ngle exposure (S	STOT SE):		
; <b>1</b>		effects		t organ	Note
Oral exposure:	No information a	vailable	No informati		-
Dermal exposure:	No information a	vailable No information available		on available	-
Inhalation exposure	: No information a	available No information available -			
Aspiration	hazard:	No infor	mation available		
Irritation a	nd corrosion:				
:	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	rabbit	-		
Eye irritation:	-	rabbit	-		
Sensitizatio	nn.				
Dermal exposure:	No information availa	able			
Inhalation exposure:	No information available				
exposure.					
Symptoms	related to the physical	, chemical and	toxicological chara	acteristics	
Oral exposure:	Swallowing may ca	nuse irritation of evels of concent g, aspiration cau	f mucosa, tingling tration may cause ses coughing, diff	sensation in the	ninal pain and vomiting.
Dermal exposure:		•	ure, resorption effe ngling sensation o		ly. Long-term exposure



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Inhalation exposi	ure:		large amounts eezing, heada	•		adequately vent	ilated perim	eter may cause
Eye exposure: Direct eye of sensation.			ntact may cau	se slight to	mod	erate irritation,	lacrimation a	and burning
Repeate	ed dos	e toxicity (sub	acute, subchro	onic, chroni	ic)			
1 21-2-2		Dose	Exposure time	Species	-,	Method	Evaluation	n Note
Subacute oral	No avail	information able	No information available	No informati available	ion	No information available	No informatio available	on -
Subacute dermal	No avail	information able	No information available	No informati available		No information available	No informatio available	on -
Subacute inhalation	No avail	information able	No information available	No informati available		No information available	No informatio available	on -
Subchronic oral	No avail	information able	No information available	No informati available	ion	No information available	No information available	on -
Subchronic dermal	No avail	information able	No information available	No informati available	ion	No information available	No information available	on -
Subchronic inhalation	No avail	information able	No information available	No informati available	_	No information available	No information available	on -
Chronic oral	No avail	information able	No information available	No informati available	ion	No information available	No informatio available	on -
Chronic dermal	No avail	information able	No information available	No informati available	_	No information available	No information available	on -
Chronic inhalation	No information available		No information available	No informati available		No information available	No informatio available	on -
- · · ·					TOT 2	UE).		
Specific target organ toxicit		1	y – repeated e pecific effects	exposure (S				Note
Subacute oral			tion available		No i	Target organisms		- Note
Subacute dermal			tion available			nformation avai		_
Subacute inhalat			tion available			nformation avai		_



Reproductive toxicity:

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Trading name:		BIO-DIFF 2 REAGENT					
Product code:	BD2-OT-	X** Dat	e of compilation:	14 November 2022	Version:	4	
Subchronic oral	No in	formation availa	ible No	information available	-		
Subchronic derma	l No in	formation availa	ble No	information available	-		
Subchronic inhalat	ion No in	formation availa	ble No	information available	-		
Chronic oral No information		formation availa	ble No	information available	-		
Chronic dermal No informatio		formation availa	ble No	information available	-		
Chronic inhalation No information		formation availa	ble No	information available	-		
CMR effe	cts (carcinog	enicity; mutager	nicity; reproductive	toxicity)			
Carcinoge	enicity:	Curre	Current studies on test animals did not indicate carcinogenic effects.				
Mutagenicity in-vitro:		Curre	Current in vitro tests did not indicate mutagenic effects.				
Genotoxicity:		No ir	No information available				
Mutagenicity in-vivo:		Curre	Current in vivo tests did not indicate mutagenic effects.				
Germ cell	mutagenicit	y: No ir	No information available				
Reproduc	tive toxicity.	No t	No toxicity on reproductive organs was determined in reproductive				

Summary of evaluation of the CMR properties:	-

organs.

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. 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)	Dose	Exposure time	Species	Method	Evaluation	Note



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Trading name:	BIO-DIFF 2 REAGENT				
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Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2.	Persistence and degradability		
	Abiotic degradation		
	Degradation half-lives	Method	Evaluation

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

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

| No information available |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|                          |                          |                          |                          |                          |
|                          |                          |                          |                          |                          |
|                          |                          |                          |                          |                          |

# 12.3. Bioaccumulative potential Octanol-water partition coefficient (log Kow) Value Concentration pH °C Method Evaluation Note No information No information

availa	ıble	available	available	
Bioconcen	tration factor (BCF)			
Value	Species	Method	Evaluation	Note



	name:					BIC	-DIFF 2	2 REAG	ENT			ge 12 of 16
Produc		BD2-OT-X** Date of compil						vembe	r 2022	V	ersion: 4	
					- 1							
No information available		No availab	inform le	nation No inform				No information available		No information available		
	Chronic ed	cotoxicity	y									
	Value		Dose		osure ime	Spe	ecies	Met	hod	Eva	aluation	Note
Chronic	toxicity on	fish	LC <sub>50</sub>	No infor availa	mation able	No infori availa	mation able	No inform availab		No infori availa	mation able	-
	toxicity on ea ( <i>Daphnia</i>		EC <sub>50</sub>	No infor avail	mation able	No infori availa	mation able	No inform availab		No infori availa	mation able	-
12.4.	Mobility in		d distributi	on in e	environm	ental o	compart	ments:				
		mation available										
	No inform	nation av	ailable									
	No inform Surface te		ailable									
			ailable °C	C	oncentra	tion		Metho	od			Note
	Surface te	nsion: No on info	°C	No	oncentra informa ailable			Metho		-		Note
	Surface te Value No information	nsion: No on info	°C ormation	No	informa		No inf	Metho		-		Note
	Value No informatic available	No n info ava	°C ormation iilable	No	informa		No inf	Metho		-		Note
Transpo	Surface te Value No informatic available  Adsorptio	No n info ava	°C ormation iilable rption ficient	No ava	informa	tion	No inf	Metho formation ple	n	ethod		Note
Transpo Soil-wat	No informatic available  Adsorptio ort H	n / deso A/D coeffeenry's coefficients	°C ormation iilable rption ficient	No ava	informa ailable og Kow	Evon No	No inf availab	Metho formation ole on rate	n	ethod	on -	
	No informatic available  Adsorptio ort H No availa	n / deso A/D coeff enry's co in able in	°C  ormation hilable  rption ficient onstant	No availa	informa ailable og Kow nformatio	Evon No	No inf availab vaporatio	Methodological Method	M No inf	ethod ormation	-	



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

12.6.	Endocrine disrupting properties				
	No known endocrine disrupting prop	erties 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 per Protection.	son authorized by the Ministry of Environmental and Nature			
13.1.2.	Waste codes/waste designations ac	cording to Law:			
	No information available				
13.1.3.	Waste treatment – relevant informa	tion:			
	No information available				
13.1.4.	Sewage disposal – relevant informa				
	Waste must not be disposed of into	o the sewage system.			
13.1.5.	Other disposal recommendations:				
	authorized by the ministry in charge	nains into the sewage system. Submit the remains to the collectors e. Do not dispose of the packaging into the sewage system. Submit norized by the ministry in charge. Do not dispose of in places where			
13.1.6.	Relevant Community provisions:				
	-				
SECTIO	N 14. Transport information				
	Transporting/shipment by road (ADR				
UN num	nber: No	t subject to transport regulations.			
UN prop	per shipping name: -				
Transpo	ort hazard class(es):				



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

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Trading name:	BIO-DIFF 2 REAGENT					
Product code:	BD2-OT-X**	Date of compilation:	14 November 2022	Version:	4	
Packing group:		-				
Environmentally haz		-				
Special precautions		-				
<u> </u>	ng/shipment by rail					
UN number:		Not subject to transport	regulations.			
UN proper shipping	name:	-				
Transport hazard cla	ass(es):	-				
Packing group:		-				
Environmentally haz	zardous:	-				
Special precautions	for user:	-				
Inland wate	erway transport (A[	ON)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	name:	-				
Transport hazard cla	ass(es):	-				
Packing group:		-				
Environmentally hazardous:		-				
Special precautions for user:		-				
Transportir	ng/shipment by sea	(IMDG)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	name:	-				
Transport hazard cla	ass(es):	-				
Packing group:		-				
Environmentally haz	zardous:	-				
Special precautions	for user:	-				
Transportir	ng/shipment by air	(ICAO-TI/IATA-DGR)				
UN number:		Not subject to transport	regulations.			
UN proper shipping name:						
Transport hazard class(es):		-				
Packing group:		_				
Environmentally hazardous:		_				
Special precautions for user:						



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

15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorization and/or rest	Authorization and/or restrictions of use			
	Authorizations:	-			
	Restrictions:	-			
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);			
	Information according 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	ent			
	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 2 REAGENT			
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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:	ning 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



#### **SAFETY DATA SHEET**

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

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

SECTIO	ON 1: Identification of t	the substan	ce/mixture a	nd of the company/undertaking	
1.1.	. Product identifier				
	Trading name:	BIO-DIFF	3 REAGENT		
	Chemical name:	-			
	Catalogue number:	BD3-OT-X	<b>*</b> *		
1.2.	Relevant identified uses of the substance or mixture and uses advised against			cture and uses advised against	
	Uses:		Buffered b	lue component of Bio-Diff kit.	
	Uses advised against:		Only the id	dentified uses are advised.	
	Reason why uses advis	s 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	y data sheet		
	Supplier:	E	BioGnost Ltd.		
	Address: Telephone number:		Medjugorska 59, Zagreb +385 1 2409997		
	Fax no.:	-	+385 1 2404039		
	e-mail of competent person:		msds@biognost.hr		
	National contact:	onal contact: -			
1.4. Emergency telephone number					
	National Protection and Rescue Dir Medical information: Other information:		rectorate:	112	
				+385 1 2348 342	
				-	

SECTIO	SECTION 2. Hazards identification					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification according to Regula	ation (EC) No 12	272/2008 (CLP)			
	Hazard class and category	/ code:	Hazard statements*:			
	Not identified as hazardous subst	tance.	-			
2.1.2.	Additional information					
	-					
*For fu	ll text of Hazard- and EU Hazard-sta	atements: see S	Section 16			
2.2.	. Label elements					
	Product identification:	BIO-DIFF 3 R	EAGENT			
	Identification number:	-				
	Authorization no.:	-				
	Hazard pictograms:	-				



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Trading name:	BIO-DIFF 3 REAGENT					
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	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	<b>Endocrine Disrupting Properties:</b>	
	No known endocrine disrupting prop	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 measures					
	General notes:	-				
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.				
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.				
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.  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.  der: Treat symptomatically.				
	Following ingestion:					
	Self-protection of the first ai					
4.2.	Most important symptoms a	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. Longterm 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:	BIO-DIFF 3 REAGENT					
Product code:	BD3-OT-X**	Date of compilation: 14 November 2022	Version: 6			

	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, 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 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: water jet						
5.2.	Special hazards arising from the substance or mixture						
	Hazardous combustion products: No information available						
5.3.	Advice for firefighters						
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.  Cool closed containers exposed to fire with water spray or vapor.						
5.4.	Additional information						
	Remove sources of heat and ignition.						
	Do not contaminate the environment with extinguishing media.						

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



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Trading name:	BIO-DIFF 3 REAGENT						
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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other section	ons
	See Section 8 for informa	ation about secure handling. ation about personal protective equipment. nation about containment.

	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:	ven	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:	Maı	nufacturer's original packaging.			
	Requirements for storage rooms and vessels:		Keep away from food and drink. Keep the containers ightly closed.			
	Advices for storage equipment:	be ı dire	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.			
	Further information on storage conditions:	and che	not place the unused material in the storage room I do not use empty containers for storing other micals. Do not store with incompatible materials (see tion 9).			



Soil (agricultural)

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

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Trading name:				ВІ	BIO-DIFF 3 REAGENT					
Product code:	BD3-OT	Γ-X**	Date	of comp	ilation:	14 Novem	ber 2022	Version: 6		
-	1									
Recommen					-					
Industrial se	ector spe	cific solutions	S:		-					
SECTION 8. Exposu		ols/personal	protec	tion						
8.1. Control par	ameters			ı						
						xposure limit				
Substance		CAS No	0		<u> </u>	term values	Biolog	gical limit valu	ies	
				pp	m	mg/m³				
-		-		-		-	No informa	tion available		
Substance - name:										
EC No: -		CAS No:	-							
DNEL										
				Indus	strial					
Pouto of ovposure:	Acute			Acute		Chronic		Chronic	C	
Route of exposure:	effect local		effe	effect systemic		effect local		effect syste	emic	
Oral	-		-			-				
Inhalation	-		-			-				
Dermal	-		-			-				
Critical physical para	meters:	solubility, flam	nmabilit	ty, corros	sivity:	-				
				Cons	umer					
Route of exposure:	A	Acute		Acute	e Chronic		ic	Chronic	C	
Route of exposure.	effe	ect local	effe	ct systemic		effect local		effect syste	emic	
Oral	-		-			-	-			
Inhalation	-		-			-	-			
Dermal	-		-			-	-			
PNEC										
Environmental prote	ction tar	get		P	NEC					
Fresh water				N	No information available					
Freshwater sediments				N	No information available					
Marine water				N	No information available					
Marine sediments				١	No information available					
Food chain				N	No information available					
Microorganisms in s	ewage tr	eatment		N	No information available					

No information available



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Air			No information available			
8.2.	Exposure controls					
8.2.1.	Appropriate engineering	controls				
	Substance/mixture relate measures to prevent expeduring 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 presposure:	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 prevent exposure:		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:		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			
	Other skin protection:		r antistatic clothing made of natural fibers (such as cotton) with long ves (EN 13034), and shoes that cover the entire foot (EN 10335).			
8.2.2.3.	Respiratory protection:	filter fo	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 preexposure:	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			

### **SECTION 9. Physical and chemical properties**



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

	Value	Method
Physical state:	liquid	No information available
Color:	blue	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:	6.3 – 7.3	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

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 REAGENT					
Product code:	BD3-OT-X**	Date of compilation:	14 November 2022	Version: 6		

	n on hazard classes as	demied in regi	unation (20) 110 12.	2,2000					
Route of exposure:	Method		Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time		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>	-		-			
6			CTOT CE'						
Specific tai	rget organ toxicity – sir		-						
	•	effects		organ		Note			
Oral exposure:	No information a		No information		-				
Dermal exposure:	No information a	vailable	No information available		-				
Inhalation exposure	: No information a	vailable	No information	on available	-				
Aspiration	hazard:	No infor	mation available						
:									
Irritation a	nd corrosion:								
	Exposure time	Species	Evaluation	Method		Note			
Skin irritation:	-	rabbit	-						
Eye irritation:	-	rabbit	-						
	ï		i	3					
Sensitizatio	on								
Dermal exposure:	No information availa	ble							
Inhalation exposure:	No information availa	ble							
•									
Symptoms	related to the physical	, chemical and	toxicological chara	cteristics					
Oral exposure:	sensation; higher lo	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, 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.  Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure							



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Product code:	BD3-OT-X**	Date of compilation: 14 N	ovember 2022	Version: 6		

Inhalation exposi	ure:		large amounts eezing, heada	•		adequately vent	ilated perim	eter may cause
Eye exposure:		Direct eye co sensation.	ntact may cau	se slight to	mod	erate irritation,	lacrimation a	and burning
Repeate	ed dos	e toxicity (sub	acute, subchro	onic, chroni	ic)			
1 21-2-2		Dose	Exposure time	Species	-,	Method	Evaluation	n Note
Subacute oral	No avail	information able	No information available	No informati available	ion	No information available	No informatio available	on -
Subacute dermal	No avail	information able	No information available	No informati available		No information available	No informatio available	on -
Subacute inhalation	No avail	information able	No information available	No informati available		No information available	No informatio available	on -
Subchronic oral	No avail	information able	No information available	No informati available	ion	No information available	No information available	on -
Subchronic dermal	No avail	information able	No information available	No informati available	ion	No information available	No information available	on -
Subchronic inhalation	No information available		No information available	No informati available	_	No information available	No information available	on -
Chronic oral	No avail	information able	No information available	No informati available	ion	No information available	No informatio available	on -
Chronic dermal	No avail	information able	No information available	No informati available	_	No information available	No information available	on -
Chronic inhalation	No information available		No information available	No informati available		No information available	No informatio available	on -
- · · ·					TOT 2	UE).		
Specific	target	1	y – repeated e pecific effects	exposure (S	IOIR			Note
Subacute oral			tion available		Target organ  No information available			- Note
Subacute dermal			tion available			nformation avai		_
Subacute inhalat			tion available			nformation avai		_



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		·				

Subchr	onic oral	No information	on available	No information available	_			
	onic dermal	No information		No information available	_			
	onic inhalation	No information		No information available	-			
Chronic		No information		No information available	-			
Chronic	c dermal	No information	on available	No information available	-			
Chronic	c inhalation	No information	on available	No information available	-			
		:		:				
	CMR effects (c	arcinogenicity;	mutagenicity; repr	oductive toxicity)				
	Carcinogenicit	y:	Current studies	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 i	n-vivo:	Current in vivo	Current in vivo tests did not indicate mutagenic effects.				
	Germ cell mut	agenicity:	No information available					
	Reproductive t	toxicity:	No toxicity on reproductive organs was determined in reproductive organs.					
	Summary of ex	valuation of the	CMR properties:					
			em properties.					
11.2.	Information or	n other hazards:						
11.2.1.	Endocrine disr	upting properti	es:					
	No known end	locrine disruptir	ng properties that	affect human health.				
11.2.2.	Other informa	tion:						
· <u></u>		·						

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			



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Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2. Pers	Persistence and degradability					
Abiotic degradation						
	Degradation half-lives	Method	Evaluation	Note		
Marine water	No information available	No information available	No information available	-		
Fresh water	No information available	No information available	No information available	-		
Air	No information available	No information available	No information available	-		
Soil	No information available	No information available	No information available	-		

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

12.3. Bio	accumulative potenti	al				
Oc	tanol-water partition	coefficier	nt (log Ko	ow)		
Value	Concentration	рН	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-
Bio	concentration factor	(BCF)				
Value	Spec	ies		Method	Evaluation	Note



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No informavailable  toxicity  Dose  sh LC50  EC50  coil redicted distribution available	Expo ti No inforr availa No inforr availa	No informavailable  osure me  mation able		Met No inform availab	chod Nation in le av	No ava Evaluat o formatio	on -	Note
toxicity  Dose  LC50  EC50  coil redicted distribution available	Expo ti No inforr availa No inforr availa	osure me mation able	Species No information available No information	Met No inform availab No inform	chod Nation in availe Nation in	Evaluat o formatio vailable o formatio	iion -	Note
Dose $EC_{50}$ Ecoil  redicted distribution available	No inforr availa No inforr availa	mation able	No information available No information	No informavailab No informa	ation in available N	o formatio vailable o formatio	on -	
Dose $EC_{50}$ Ecoil  redicted distribution available	No inforr availa No inforr availa	mation able	No information available No information	No inform availab No inform	ation in available N	o formatio vailable o formatio	on -	
sh LC <sub>50</sub> EC <sub>50</sub> soil redicted distribution available	No inforr availa No inforr availa	mation able	No information available No information	No inform availab No inform	ation in available N	o formatio vailable o formatio	on -	
EC <sub>50</sub> coil redicted distribution available	inforr availa No inforr availa	mation able	information available No information	inform availab No inform	ation in le av N ation in	formation vailable o formation		
oil redicted distributi ion available	inforr availa	mation	information	inform	ation in	formatio	on -	
redicted distributi ion available	ion in e				ile av	<i>r</i> aliable		
ion available	ion in e							
		nvironme	ntal compa	rtments:				
ion:								
Value     °C     Concentration     Method       Importantion relable     No information available     No information available     No information available		Concentration Method			Note			
		-						
/ desorption								
O coefficient ary's constant	lo	g Kow	Evapora	tion rate	Meth	od		Note
information le					mation No information available		-	
information le					No inform available	ation	-	
information le					No inform available	ation	_	
le	coefficient y's constant information information information information a	coefficient y's constant  information e information no in availa information no in availa information No in availa availa	coefficient y's constant  information info	coefficient y's constant  Information info	coefficient y's constant  Information available  Information available	coefficient y's constant  log Kow Fivaporation rate  information available  T and vPvB assessment  Evaporation rate Meth Mo information available  No information available  T and vPvB assessment	coefficient y's constant  log Kow Evaporation rate  information available  information No information available  information available  information No information available  information No information available  information available  T and vPvB assessment  Evaporation rate  Method  No information available  No information available  No information available  T and vPvB assessment	coefficient y's constant  log Kow Evaporation rate  Method  information available  information No information available  information No information available  information No information available  information No information available  No information available  T and vPvB assessment



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12.6.	Endocrine disrupting properties				
	No known endocrine disrupting prop	erties 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 per Protection.	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.			
13.1.2.	Waste codes/waste designations according to Law:				
	No information available				
13.1.3.	Waste treatment – relevant information:				
	No information available				
13.1.4.	Sewage disposal – relevant information:				
	Waste must not be disposed of into the sewage system.				
13.1.5.	Other disposal recommendations:				
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.				
13.1.6.	Relevant Community provisions:				
	-				
SECTIO	N 14. Transport information				
	Transporting/shipment by road (ADR				
UN num	nber: No	t subject to transport regulations.			
UN prop	per shipping name: -				
Transpo	ort hazard class(es):				



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Trading name: BIO-DIFF 3 REAGENT					
Product code:	BD3-OT-X**	Date of compilation:	14 November 2022	Version:	6
Packing group:		-			
Environmentally haz		-			
Special precautions		-			
<u> </u>	ng/shipment by rail				
UN number:		Not subject to transport	regulations.		
UN proper shipping	name:	-			
Transport hazard cla	ass(es):	-			
Packing group:		-			
Environmentally haz	zardous:	-			
Special precautions	for user:	-			
Inland wate	erway transport (A[	ON)			
UN number:		Not subject to transport	regulations.		
UN proper shipping	name:	-			
Transport hazard class(es):		-			
Packing group:		-			
Environmentally hazardous:		-			
Special precautions for user:		-			
Transportir	ng/shipment by sea	(IMDG)			
UN number:		Not subject to transport	regulations.		
UN proper shipping	name:	-			
Transport hazard cla	ass(es):	-			
Packing group:		-			
Environmentally haz	zardous:	-			
Special precautions	for user:	-			
Transportir	ng/shipment by air	(ICAO-TI/IATA-DGR)			
UN number:		Not subject to transport	regulations.		
UN proper shipping	name:	-			
Transport hazard class(es):		-			
Packing group:		-			
Environmentally haz	zardous:	-			
<i>-</i>	for user:	-			



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

15.1.	Safety, health and enviror	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations					
	Authorization and/or restrictions of use					
	Authorizations:	-				
	Restrictions:	-				
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);				
	Information according 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 assessme	ent				
	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 REAGENT		
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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



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

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

SECTI	ON 1: Identification of	the substance	e/mixture	e and of the company/undertaking	
1.1	Product identifier				
	Trading name:	BUFFER SO	LUTION, p	oH 6.8	
	Chemical name:	-			
	Catalogue number:	PUF68-OT-	X**		
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against	
	Uses:		Buffer so	olution for use in hematology, 6 mM.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplier	of the safety	data shee	t	
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997 +385 1 2404039 <u>msds@biognost.hr</u>		
	Telefax.:				
	e-mail of competent p	erson:			
	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	ECTION 2. Hazards identification				
2.1	Classification of the substance	Classification of the substance or mixture			
2.1.1	Classification according to R	egulation (EC) No 1	272/2008 (CLP)		
	Hazard class and cate	egory code:	Hazard statements*:		
	Not identified as hazardous	substance.	-		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazaı	rd-statements: see	SECTION 16		
2.2	Label elements				
	Product identification:	BUFFER SOLUT	ION, pH 6.8		
	Identification number:	ion number: -			
	Authorization number: -				
	Hazard pictograms:	-			



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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	rties:
	No known endocrine disrupti	ng properties
	<b>Results of PBT and vPvB ass</b> PBT or a vPvB.	sessment: According to the results of its assessment, this substance is not a

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

SECTION	ECTION 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 eff	fects, both acute and delayed			
	Following inhalation:	No information available.			
	Following skin contact:	No information available.			
	Following eye contact:	No information available.			



### SAFETY DATA SHEET rding to Regulation (EC) No. 1907/

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

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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 medic	cal attention and special treatment needed
	-	

SECTI	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 environment	ent with extinguishing media.			

SECTIO	N 6. Accidental release meas	ures				
6.1	Personal precautions, protective equipment and emergency procedures					
6.1.1.	For non-emergency personnel					
	Protective equipment:	Use personal protective equipment (see Section 8).				
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.				
	Emergency procedures: Mark the area using proper signs.					
6.1.2.	For emergency responders:					
	Use protective equipment; in a (see Section 8).	case of inadequate ventilation use adequate airways protective equipment				
6.2	Environmental precautions:					
	Do not dispose of in sewage, or 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 con-	tainment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.				
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents.				
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).				
6.4	Reference to other sections					



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Trading name:		BUFFER SOLUTION	I, 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	n:	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:		ghtly closed and upright set containers in a ated storage roomsat temperatures ranging 25 °C.		
	Packaging materials:	Manufactu	urer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away	y from food and drink. Keep the containers sed.		
	Advices for storage equipment:	must be re	ge must be made of hard material; floors esistant to chemicals. There must be no drain sly leads into sewage system. Secure proper n.		
	Further information on storage conditions:	and do no	ace the unused material in the storage room of 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:	_			

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



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Trading name	2:					BUFFER SOLUTION, pH 6.8						
Product code:		PUF68-0	OT-X** Date		of c	ompila	tion:	22 [	Dec 2022	022 Version:		
	·								•			
-				-		-		-			-	
Substance nam	ie:	-	1				<u> </u>					
EC No:		-	CAS No	):	-							
DNEL												
				1	li	ndus	strial			1		
Route of		Acu			Acute			Chro			Chronic	
exposure:		effect	local	effec	t system	nic		effect l	ocal		effect systemic	
Oral	-   -			-			-			-		
Inhalation	-			-			-			-		
Dermal				-			-			-		
Critical physica	l parar	meters: s	solubility,	flamma								
		T		1		onsi	umer					
Route of			cute		Acute			Chro			Chronic	
exposure:		effec	t local		t system	nic		effect l	ocal		effect systemic	
Oral		-		-			-			-		
Inhalation		-		-			-			-		
Dermal		-		-			-			-		
PNEC						Τ						
Environmental	protec	ction tar	get				NEC					
Fresh water						+	o inform					
Freshwater sed	iment	S					o inform					
Marine water						+	o inform					
Marine sedime	nts					+	o inform					
Food chain						No information available  No information available						
Microorganism		ewage tr	eatment			-						
Soil (agricultura	al)						o inform					
Air						No	o inform	nation a	vailable	e		
8.2 Ex	nosura	e contro	lc									
	<u> </u>			controls								
•			ineering ire related				•				ooms. Use persona rink or smoke in t	
pro	event	exposur	e during	identifie	ed uses:		orkspace		nent. L	o not eat, u	THIN OF SHIOKE III C	.110



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Trading name:		BUFFER SOLUTION	I, pH 6.8		
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	Structural measures to prevent exposure:		In accordance with Section 7.			
	Organisational measures to prevent exposure:		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 entire face in case of higher levels of concentration in air.				
8.2.2.2. Skin protection						
	Hand protection:	Protective 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	ection 6			
	Structural measures to prevent exposure:	Use m	odern equipment.			
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the lace.			
	Technical measures to prevent exposure:	See Section 6				

SECTI	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	l, 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
	рН:	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
9.2	Other information		
	-		

SECTION 10. Stability and reactivity		
10.1	Reactivity:	No information available
10.2	Chemical stability:	No information available
10.3	Possibility of hazardous reactions:	No information available
10.4	Conditions to avoid:	No information available
10.5	Incompatible materials:	No information available
10.6	Hazardous decomposition products:	No information available

11.1 Informa	ition on hazard o	classes as defined in R	egulation (EC) No 1272/2	2008	
Acute to	oxicity:				
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results
Oral:	-	No information available	No information available	No information available	_
Dermal:	-	No information available	No information available	No information available	_
Inhalation:	-	No information available	No information available	No information available	_



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								Pa	ge 8 of 1	6	
Trading name:				BUFFER S	OLUTIO	۷, pH 6	.8				
Product code:	Р	UF68-OT-X**		Date of comp	ilation:	22 De	ec 2022	Ve	rsion:	4	
	8			1							
			ific effects		Target organ				Note		
Oral:	١	No information available		No i	nformatio	n availal	ole -	-			
Dermal:	١	No information	available	No i	nformatio	n availal	ole -	-			
Inhalation:	١	No information	available	No i	nformatio	n availal	ole -	-			
Aspirat	ion ha	zard:		No informatio	n available	e.					
Irritatio	n and	corrosion									
		Exposur	e time	Species	Evalua	ation	Method		Note		
Skin corrosion/irritat	ion:	-		-	-						
Serious eye damage/irritation			-	-		-	-				
Sensitiz	zation										
Skin sensitizatio	n:	-									
Respiratory sens	sitizati	on: -									
Sympto	oms re	lated to the pl	nysical, chem	ical and toxico	logical cha	aracteris	tics				
Oral exposure:		No informati	on available								
Dermal exposur	e:	No informati	on available								
Inhalation expos	sure:	No informati	on available								
Eye exposure:		No informati	on available								
Repeat	ed do	se toxicity (sub	acute, subch	ronic, chronic)	·						
		Dose	Exposure time	Species	Meth	nod	Evaluati	on	Note		
Subacute oral	No avai	information ilable	No information available	No information available	No infor availa	mation able	No information available		-		
Subacute dermal	No avai	information ilable	No information available	No information available	No infor availa	mation able	No information available				

No

information

available

No information

available

Subacute

inhalation

No

information

available

No

information

available

No

information

available



Reproductive toxicity:

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r roduct code.	10	100-01-7	De	ate of compila	tion.	22 De	C 2022	٧ ر	2131011.	٦
Subchronic oral	No availa	information able	No information available	No information available	No infor availa	mation able	No information available	on	-	
Subchronic dermal	No availa	information able	No information available	No information available	No infor availa	mation able	No information available	on	-	
Subchronic inhalation	No availa	information able	No information available	No information available	No infor availa	mation able	No information available	on	-	
Chronic oral	No information available		No information available	No information available	No infori availa	mation able	No information available		-	
Chronic dermal	No availa	information able	No information available	No information available	No infori availa	mation able	No information available	on	-	
Chronic inhalation				No information available	No infori availa	mation able	No information	on	-	
	i		:	i			i		:	
Specific	target	organ toxicit	y – repeated e	xposure (STOT	RE):					
			Specific effec	cts		Target o	rgan		Note	
Subacute oral		No informa	ntion available		No information available -			-		
Subacute derma		No informa	ntion available		No information available		-			
Subacute inhalat	tion	No informa	ntion available		No information available		-			
Subchronic oral		No informa	ntion available		No information available		-			
Subchronic dern	nal	No informa	ntion available		No in	formation	n available	-		
Subchronic inha	lation	No informa	ntion available		No information available		-			
Chronic oral			ntion available				n available	-		
Chronic dermal			ntion available				n available	-		
Chronic inhalation	on	No informa	ntion available		No in	formation	n available	-		
			y; mutagenicity	y; reproductive						
Carcino				No inform						
Mutage		n vitro:			No information available					
Genoto	<u>-</u>	•			No information available					
Mutage				No information available						
Germ c	eli muta	agenicity:		No information available						

No information available



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

#### 12.2 Persistence and degradability



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



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		!						Page 12 of 1	Ь
Trading	name:		В	UFFER SO	LUTION	, pH 6.	.8		
Product	code:	PUF68-OT-X**	Date	of compila	tion:	22 De	c 2022	Version:	4
	nic toxicity on acea ( <i>Daphnia</i> )		No No No information available available available		1		1 -		
12.4	Mobility ir	n soil							
	•	predicted distribut	ion in environme	ental compa	rtments:				
		ation available							
	Surface te	nsion:							
	Value	°C	Concentrat	tion	Meth	Method		Note	
	No informatio available	No information available	No informat available	ion No i avail	nformatio able	on	-		
Transpor	t .	n / desorption  A/D coefficient  enry's constant	log Kow	Evapora	ation rate		Method	Note	<u> </u>
Soil-wate	No.	information	No informatio	•	rmation		nformation		
Water-ai	No	information	No informatio		rmation		nformation	_	
Soil-air	No availa	information able	No informatio available	n No info		No ir	nformation able	-	
12.5.	Results of	PBT and vPvB asse	ssment						
	Based on a	available data, the	product does no	ot contain ar	ny PBT or	vPvB su	ıbstances.		
12.6.	Endocrine	disrupting propert	ies						
	No known	endocrine disrupt	ing properties th	nat affect the	environ	ment.			
12.7.	Other adv	erse effects							
	No advers	e effects are expec	ted.						
SECTION	I 12 Dien	osal consideration							
13.1		osal consideration eatment methods	15						
. 3. 1	Traste ti	outment metrious							



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



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

SECTION	ECTION 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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	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16	
		December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);	
	Information according 1999, guideline)	/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	ON 16. Other information	
16.1	Indication of changes:	-
16.2	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  IMDG: International Maritime Code for Dangerous Goods  IATA: International Air Transport Association  GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances  CAS: Chemical Abstracts Service (division of the American Chemical Society)  DNEL: Derived No-Effect Level (UK REACH)  LC50: Lethal concentration, 50 percent  LD50: Lethal dose, 50 percent  PBT: Persistent, Bioaccumulative and Toxic  vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-



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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:	-			
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product)  We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to chemical safety assessment
-



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SECTI	ON 1: Identification of	the substance	e/mixture	and of the company/undertaking
1.1	Product identifier			
	Trading name:	BUFFER SO	LUTION, p	H 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:		Buffer so	olution for use in hematology, 6 mM.
	Uses advised against:		Only the	e identified uses are advised.
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.	
1.3	Details of the supplier of the safety data sheet			
	Supplier:		BioGnost Ltd.	
	Address:		Medjugorska 59, Zagreb	
	Telephone number:		+385 1 2409997	
	Telefax.:		+385 1 2404039	
	e-mail of competent p	erson:	msds@b	<u>piognost.hr</u>
	National contact:		-	
1.4	Emergency telephone	number		
	National Protection ar	nd Rescue Dire	ectorate:	112
	Medical information:			+385 1 2348 342
	Other information:			-

SECTIO	ECTION 2. Hazards identification					
2.1	Classification of the substance or mixture					
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)					
	Hazard class and cate	egory code:	Hazard statements*:			
	Not identified as hazardous	substance.	-			
2.1.2.	Additional information					
	-					
*For fu	ll text of Hazard- and EU Hazar	d-statements: see	SECTION 16			
2.2	Label elements					
	Product identification:	BUFFER SOLUT	ION, pH 7.2			
	Identification number:	-				
	Authorization number: -					
	Hazard pictograms:	-				



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	Signal word:	-			
	Hazard statements:	-			
	Precautionary statements:	-			
	Supplemetal hazard information (EU):	-			
2.3	Other hazards				
	Endocrine Disrupting Prope	rties:			
	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. Composition/information on ingredients									
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)					
-	-	-	Contains no hazardous substances.	-					

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



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

SECTI	SECTION 5. Firefighting measures						
5.1	Extinguishing media						
	Suitable extinguishing media:	Small fire - water spray, dry powder, $CO_2$ Large fire - water spray or alcohol-resistant foam					
	Unsuitable extinguishing media:	No information available					
5.2	Special hazards arising from the s	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	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	ECTION 6. Accidental release measures						
6.1	Personal precautions, protective equipment and emergency procedures						
6.1.1.	For non-emergency personnel						
	Protective equipment:	Use personal protective equipment (see Section 8).					
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.					
	Emergency procedures: Mark the area using proper signs.						
6.1.2.	For emergency responders:						
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).						
6.2	Environmental precautions:						
	Do not dispose of in sewage, or Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National rate (NPRD) on 112.					
6.3	Methods and material for con-	tainment and cleaning up					
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.					
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents.					
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).					
6.4	Reference to other sections						



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See Section 7 for information about secure handling.

See Section 8 for information about personal protective equipment.

See Section 13 for information about containment.

SECTIO	ON 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:		Use in well ventilated storage rooms.		
	Measures to prevent aerosol and dust generation	n:	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 incom	compatibilities			
	Technical measures and storage conditions:		ghtly closed and upright set containers in a ated storage roomsat temperatures ranging 25 °C.		
	Packaging materials:	Manufactu	urer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away	y from food and drink. Keep the containers sed.		
	Advices for storage equipment:	must be re	ge must be made of hard material; floors esistant to chemicals. There must be no drain sly leads into sewage system. Secure proper n.		
	Further information on storage conditions:	Do not place the unused material in the storage rand do not use empty containers for storing other chemicals. Do not store with incompatible materi (see Section 10).			
7.3	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	_			

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



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										T		
-				-		-	-		-		-	
Substance name:		-						Π				
EC No:		-	CAS No	):	-							
DNEL												
						Indu	strial					
Route of		Acu			Acute			Chro			Chronic	
exposure:		effect	local	effec	t syste	mic		effect	local		effect systemic	
Oral	-			-			-			-		
Inhalation	-			-			-			-		
Dermal	-					-			-			
Critical physical pa	arar	neters: s	olubility,	flamma	ability,	corro	sivity:	-				
						Cons	umer					
Route of			Acute			Chronic			Chronic			
exposure:	. ,		t syste	mic	ic effect local			effect systemic				
Oral		-		-						-		
Inhalation		-		-			-		-	-		
Dermal		-		-			-					
PNEC												
Environmental pro	otec	tion tar	get			P	NEC					
Fresh water						N	o inforn	nation a	availabl	e		
Freshwater sedim	ents	5				N	No information available					
Marine water						N	No information available					
Marine sediments						N	No information available					
Food chain						N	No information available					
Microorganisms in	n se	wage tre	eatment			N	No information available					
Soil (agricultural)						No information available						
Air						N	o inforn	nation a	availabl	е		
8.2 Expos	sure	control	S									
			ineering	controls	5							
Subst	tanc	ce/mixtu	re related	d meası	ıres to	р	•	e equip			ooms. Use person Irink or smoke in t	



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	Structural measures to prevent exposure:		In accordance with Section 7.			
	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent ex	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Se stations for rinsing eyes and showering.				
8.2.2.	Personal protection equipment					
8.2.2.1.	Eye and face protection:	levels	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:	Protective 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	ection 6			
	Structural measures to prevent exposure:	Use m	odern equipment.			
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the lace.			
	Technical measures to prevent exposure:					

SECTI	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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	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
	рН:	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
9.2	Other information		
	-		

SECTIO	SECTION 10. Stability and reactivity				
10.1	Reactivity:	No information available			
10.2	Chemical stability:	No information available			
10.3	Possibility of hazardous reactions:	No information available			
10.4	Conditions to avoid:	No information available			
10.5	Incompatible materials:	No information available			
10.6	Hazardous decomposition products:	No information available			

11.1 Informa	ntion on hazard	classes as defined in R	egulation (EC) No 1272/2	2008	
Acute to	oxicity:				
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results
Oral:	-	No information available	No information available	No information available	_
Dermal:	-	No information available	No information available	No information available	_
Inhalation:	-	No information available	No information available	No information available	_



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	,		:		:			:	1
		Spec	ific effects		Target o	organ		Note	
Oral:	١	lo information	available	No in	formation a	available	-		
Dermal:	١	lo information	available	No in	formation a	available	-		
Inhalation:	١	lo information	available	No in	formation a	available	-		
Aspirat	ion ha	zard:		No information	available.				
Irritatio	n and	corrosion							
		Exposur	e time	Species	Evaluati	on M	lethod	Note	
Skin		-		-	-	_		-	
corrosion/irritat	ion:								
Serious eye damage/irritation	on	-		-	-	-		-	
- aumage, mitatio									
Sensitiz	zation								
Skin sensitizatio	n:	-							
Respiratory sens	sitizatio	on: -							
Sympto	oms re	lated to the pl	nysical, chemi	cal and toxicolo	gical chara	acteristics			
Oral exposure:		No informati	on available						
Dermal exposur	e:	No informati	on available						
Inhalation expo	sure:	No informati	on available						
Eye exposure:		No informati	on available						
Repeat	ed dos	se toxicity (sub	acute, subch	ronic, chronic)					
		Dose	Exposure time	Species	Method	d	Evaluatior	n Note	
Subacute oral	No avai	information ilable	No information available	No information available	No informa availab	ation	No informatio available	on -	
Subacute dermal	No avai	information ilable	No information available	No information available	No informa availab	ation	No informatio available	on -	

No

information

available

No information

available

Subacute

inhalation

No

information

available

No

information

available

No

information

available



Reproductive toxicity:

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Product code.	PU	F72-U1-X***	Da	ate of compila	tion.	22 De	C 2022	VE	ersion. <sup>2</sup>
Subchronic oral	No availa	information able	No information available	No information available	No infor availa	mation able	No information available	on	-
Subchronic No information dermal		No information available	No information available	No infor availa	mation able	No information available	on	-	
Subchronic No information inhalation available		No information available	No information available	-			on	-	
Chronic oral	No availa	information able	No information available	No information available	No infor availa	mation able	No informatio available	on	-
Chronic dermal	No availa	information able	No information available	No information available	No infor availa	mation able	No information available	on	-
Chronic inhalation	No availa	information able	No information available	No information available	No infor availa	mation able	No informatio available	on	-
				•					
Specific	target	organ toxicit	y – repeated e	exposure (STOT	RE):				
			Specific effec	cts		Target o	organ		Note
Subacute oral		No informa	tion available		No in	formatio	n available	-	
Subacute derma		No informa	ation available		No information available		-		
Subacute inhalat	ion	No informa	ation available		No information available		-		
Subchronic oral		No informa	ation available	ion available		No information available		-	
Subchronic dern	nal	No informa	ation available	le No		No information available		-	
Subchronic inha	lation		ation available		No information available		-		
Chronic oral			ation available		No information available		-		
Chronic dermal No information a					No information available		-		
Chronic inhalation	on	No informa	ation available		No in	formatio	n available	-	
			y; mutagenicity	y; reproductive					
Carcinogenicity:			No inform						
Mutage	·····	n vitro:		No inform					
Genoto				No inform					
Mutage				No inform					
Germ co	en muta	agenicity:		ino intorm	No information available				

No information available



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

#### 12.2 Persistence and degradability



PUF72-OT-X\*\*

Trading name:

Product code:

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	c degr	radation								
	D	egradation	half-li	ves	l	Method	Evaluatio	n		Note
Marine water	No	informatio	n availa	able	No in availa	formation ble	No informatio available	n	-	
Fresh water	No	informatio	n availa	able	No in availa	formation ble	No informatio available	n	-	
Air	No	informatio	n availa	able	No in availa	formation ble	No informatio	n	-	
Soil	No	informatio	n availa	able	No in availa	formation ble	No informatio available	n	-	
Riode	gradat	tion								
% Degradati			e (days	)		Method	Evaluatio	n		Note
No information		No	inform		No in	formation	No informatio			rmation
available		available			availa	DIE	available		available	
		ative poter		: -: - · · · · ·	la a Kan					
	ol-wat Conc	ative poter ter partition centration		Н	log Kov °C	v) Method	Evalu	ation		Note
Octan Value	ol-wat Conc	ter partitio	n coeff p	Н	°C	Method		ation	-	Note
Octan Value 	ol-wat	ter partitio	p -	Н	°C	Method		ation	-	Note
Octan Value 	ol-wat	ter partition centration ation facto	p -	Н	°C -	Method			-	Note
Octan Value Biocor Value No information	Conc	ter partition centration ation facto	p coeff	H	°C	Method  Method  formation	-	ion	-	
Octan Value Biocor Value No information	Conc	ter partition centration ation facto Spe	p r (BCF)	H	°C - No inf	Method  Method  formation	Evaluat No informat	ion		
Octan Value Biocor Value No information	Conc	ter partition centration ation facto Spe	p r (BCF)	H	°C - No inf	Method  Method  formation	Evaluat No informat	ion		
Octan Value Biocor Value No information available	ncentr	ter partition centration ation facto Spe	p r (BCF)	H	°C - No inf	Method  Method  formation	Evaluat No informat	ion		
Value Biocor Value No information available	ol-wat	ter partition tentration factor Special Specia	p r (BCF)	ation	°C - No inf	Method  Method  formation	Evaluat No informat	ion ion		



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Trading	name:		BU	IFFER SOL	JTION,	pH 7.	2		
Product code: PUF72-OT-X**		PUF72-OT-X**	* Date of compilation:			22 Dec 2022		Version:	4
Chronic toxicity on crustacea ( <i>Daphnia</i> )		No No information available available			No No information available available		-		
12.4	Mobility ir	n soil							
	Known or	predicted distributi	on in environmer	ntal compart	ments:				
	No inform	ation available							
	Surface te	nsion:							
	Value	°C	Concentration	on	Metho	od		Note	
	No informatio available	No information available	No information	on No inf availal	ormatio ole	n	-		
	Adsorptio	n / desorption							
Transpo	rt	A/D coefficient enry's constant	log Kow Evapo		on rate	rate Method		Note	!
Soil-wat	er No availa	information able	No information available	No inform available	nation	No ir availa	nformation able	-	
Water-a	ir No availa	information able	No information available	No inform available	nation	No ir availa	nformation able	-	
Soil-air	No availa	information able	No information available	No inform available	nation	No ir availa	nformation able	-	
12.5.	Results of	PBT and vPvB asses	ssment						
	Based on	available data, the p	product does not	contain any	PBT or v	vPvB su	bstances.		
12.6.	Endocrine	disrupting propert	ies						
	No known	endocrine disrupti	ng properties tha	t affect the	environr	ment.			
12.7.	Other adv	erse effects							
	No advers	e effects are expect	ted.						
		osal consideration	S						
13.1	Waste tr	reatment methods							



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



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

SECTI	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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	None	
15.2	Chemical safety assessme	ent
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);

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



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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:	-		
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product)  We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

ANNEX: Exposure scenario resulting to chemical safety assessment	
-	