

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 ident	Only the identified uses are advised.		
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.			
1.3.	Details of the supplier of the safety data sheet				
	Supplier:	BioGnost Ltd.			
	Address:	Medjugorska 59, Zagreb			
	Telephone number:	+385 1 2409997			
	Telefax:	+385 1 24040	39		
	e-mail of competent person:	msds@biognost.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 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	* For 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:	GHS06 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	
	Results of PBT and vPvB 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 ₂			
	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	TION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency pe	ersonnel			
	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.		
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:	of 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	ctions	
	See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal 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	tibilities	
	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: Do not place the and do not use e chemicals. Do not (see Section 10).				do not use emp	oty contai	ners for stori	ng other			
7.3.	Specific er	nd use(s)								
	Recomme	ndations:			-					
	Industrial sector specific solutions: -									
SECTIO	ON 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	200	200 260 (7.0 mg/g c		nol/mol of cre/ /g of creatinics shift urinary	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	1			
Route			Acute		Acute .		Chron			ronic
exposi	ıre:	effe	ect local	ette	ect systemi	С	effect lo	cal	effect :	systemic
Oral		-	, 3	-	, 3		-		-	
Inhalati	ion	260 m (metha	_				260 mg/m ³ (methanol)		260 mg/m ³	(methanol)
Dermal	<u> </u>	-		40 mg/kg (methanol)				40 mg/kg (methanol)	
Critical	physical par	rameters:	solubility, fl	ammabili	ty, corrosiv	vity:		-		
					Consur	ner				
		Acute		Acute		Chronic			ronic	
exposi	ire:	effe	ect local		ect systemi		effect lo	cal		systemic
Oral		- -	/m 3		kg (methan	OI)	- 		8 mg/kg (n	iethanol)
Inhalation 50 mg/m³ 50 mg/m³ (methanol) (methanol)				50 mg/m ³ (methanol)		50 mg/m ³ (methanol)				
Dermal	l	-		8 mg/k	kg (methan	ol)			8 mg/kg (n	nethanol)
PNEC										



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Environm	ental protection target	PNEC			
Fresh wat	er	154 mg/l (methar	154 mg/l (methanol)		
Freshwate	er sediments	570.4 mg/kg (met	thanol)		
Marine w	ater	15.4 mg/l (metha	nol)		
Marine se	ediments	No information a	vailable		
Food cha	in	No information a	vailable		
Microorg	anisms in sewage treatment	100 mg/l (methar	nol)		
Soil (agric	cultural)	23.5 mg/kg (meth	nanol)		
Air		No information a	vailable		
		-			
8.2.	Exposure controls				
8.2.1.	Appropriate engineering measures				
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to prevent exposure:	No information available			
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's nfluence 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:		glasses. Use equipment for eye approved under appropriate government 66(EU).		
8.2.2.2.	Skin protection:				
		ecification of EC Dire 1374. Il contact:	o be used must comply with the ective 2016/425 and the related standard		
	Hand protection.	Glove material: Glove thickness			
	Hand protection:		time: > 480 min		
		lash contact:			
		Gloves materia	l: viton (R)		
		Glove thickness	s: 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

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



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	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.			

SECTIO	ON 11. To	cicological information				
11.1.	Informat	ion on hazard classes as	defined in Regu	lation (EC) No 1272	/2008	
	Acute to	xicity:				
Route exposu		Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:		No information available	rat	LD ₅₀	-	125.13 mg/kg (methanol)
Dermal:		No information available	rabbit	LD ₅₀	-	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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o information available organ toxicity - s Specific efformation availation	rat single exposu effects able able No	No inf No inf Eyes	Target cormation	04.2023. 4 h organ available available Method	Note Note Note Note Note Note Note Note Amage to organs
available organ toxicity - s Specific efformation availation ava	single exposureffects able able No	No inf No inf Eyes information av	Target of comment on c	organ available available Method	(methanol) Note mixture causes damage to organs Note
Specific efformation availation availation availation availation availation availation	effects able able No	No inf No inf Eyes information av	ormation formation vailable	available available Method	- mixture causes damage to organs Note
Specific efformation availation availation availation availation availation availation	effects able able No	No inf No inf Eyes information av	ormation formation vailable	available available Method	- mixture causes damage to organs Note
formation availation formation availation av	able able No Spe	No inf Eyes information av	ormation formation vailable	available available Method	- mixture causes damage to organs
formation availand	No Spe	information av	vailable	Method	mixture causes damage to organs Note
rd: orrosion	No e Spe	information av			damage to organs Note
orrosion	e Spe	cies Eval			
			uation		
			uation		
					resulting in rough and chapped skin
Serious eye				_	irritations of mucous membranes
Does not cause s	sensitization.				
No information a	available				
ted to the physic	cal, chemical	and toxicologi	cal charac	cteristics:	
		•	•	-	,
		J .	l exposure	e may cause	absorption and greater
•	•		_		or concentration, dizzine
a damage,blind	ness, irrevers				
toxicity (subscu	te subchroni	ic chronic)			
-			N 4.	othod	Evaluation No
t á r	no information and to the physicach and bowel is minal pain. Absolute level of irribility of delayed siness, headaches moderate irribility and adamage, blind later, after the toxicity (subacultoxicity (subacultoxicity)	ach and bowel irritation, acid minal pain. Absorption may on num level of irritation, defatt pility of delayed systemic effor ys irritation and possible lun- siness, headache. Absorption to moderate irritation due to a damage, blindness, irrevers later, after the absorbtion.	need to the physical, chemical and toxicological and bowel irritation, acidosis, drop in be minal pain. Absorption may cause toxic effects are level of irritation, defatting; prolonged polity of delayed systemic effects. The process of the physical and toxicological actions are level of irritation, defatting; prolonged polity of delayed systemic effects. The process of the physical action and possible lung damage dues in the process of the process of the physical action and possible lung damage dues in the process of the physical action and possible lung damage dues in the process of the physical action and possible lung damage of the physical action	No information available eed to the physical, chemical and toxicological chara ach and bowel irritation, acidosis, drop in blood pre- minal pain. Absorption may cause toxic effects. Dam num level of irritation, defatting; prolonged exposur polity of delayed systemic effects. ys irritation and possible lung damage due to high lesiness, headache. Absorption may cause toxic effect to moderate irritation due to vapor, conjunctivitis, la a damage, blindness, irreversible damage of the opt later, after the absorbtion.	need to the physical, chemical and toxicological characteristics: ach and bowel irritation, acidosis, drop in blood pressure, feeling minal pain. Absorption may cause toxic effects. Damage to liver, num level of irritation, defatting; prolonged exposure may cause bility of delayed systemic effects. ys irritation and possible lung damage due to high levels of vapoiness, headache. Absorption may cause toxic effects. to moderate irritation due to vapor, conjunctivitis, later chemosi a damage, blindness, irreversible damage of the optical nerve. Valater, after the absorbtion.



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

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



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	CMR effects (carcinogenicity, mutagenicity, 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 informations:								
	-								

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



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Crustacea:		EC ₅₀	48 hou	rc i	information ilable	No inforr availa	mation able	No information available		-	
Algae/aquati plants:	С	IC ₅₀	72 hou	rc	information ilable	No inforr availa	mation able	No inform availal		-	
Other organi	sms	-	_	-		-		-		-	
12.2. Pers	istence	e and degrada	ability								
		gradation									
		<u>S</u> Degradation h	alf-lives		Method			Eval	luation		Note
Marine water		information a			information avai	lable	No in	nformation available -			-
Fresh water	esh water No information available				information avai	lable	e No information available			-	
Air	No information available			No	information ava	lable	ble No information available			-	
Soil	No	information a	vailable	No	information avai	lable	No in	formati	on ava	ilable	-
Biod	degrad	ation		1							
% Degradation Time (days)				Method		valuatio			No	te	
-		-		-		No in availa	formation ble	on	_		
12.3. Bioa	ccumu	ulative potenti	al								
Octa	anol-w	ater partition	coefficie	ent (log K	ow)	1			-		
Value	Cor	ncentration	рН	°C	Method		Evalua			N	ote
-	No availa	information able	-	-	-		o inform vailable	ation	-		
Biod	oncen	tration Factor	(BCF)								
Value		Spec	ies		Method		Evaluatio	on		No	ote
No informati available	on	No information available			No information available		No information available		No information available		



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	Chronic ecotox	icity									
	Value	Dose	Exposure time		Species	Me	thod	Eval	luation		Note
Chronic	toxicity on fish	LC ₅₀	No information available		o Iformation Vailable	No inform availal	i availahle				-
	toxicity on ea (Daphnia)	EC ₅₀	No information available	1	o Iformation vailable	No inform availal		No info			-
12.4.	Mobility in soil										
	Known or predi	icted distribut	ion in enviro	nmen	tal compartr	nents:					
	No information	available									
	Surface tension	:									
	Value		°C		Concentrati	on		Metho	od		Not
	No information No ir available available		nformation	No information available			No information available			9	-
	Adsorption / de	•	1		1						
Transpo	ort í	oefficient s constant	log Kov	W	Evaporatio	on rate	Method		Note		
Soil-Wa	nter No available	information	No inform available	ation	No informa	ation	No information available		-	-	
Water-	Air No available	information	No inform available	ation	No informa	ation	No info		-		
Soil-Air	No available	information	No inform available	ation	No informa	ation	No info		-		
12.5.	Results of PBT a					DDT '	DD.				
12.6	Substance(s) in			et the	criteria for	RRI OL A	-VR				
12.6.	Endocrine disru	· • • • • • • • • • • • • • • • • • • •				, .					
	The substance/ according to RE Regulation (EU)	EACH Article 5	7(f) or Comr	nissio	n Delegated						•



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Trade name:		BIO-DIFF 1 R	EAGENT		
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12.7.	Other adverse effects			
	No adverse effects are expecte	ed.		
SECTION	N 13. Disposal considerations			
13.1.	Waste treatment methods			
13.1.1.	Product/Packaging disposal:			
	Waste material must be disposed of according to the national and local rules and regulations. Do not mix with other sorts of waste. Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.			
1212	Masta sadas (wasta dasignat	ions according to Laur		
13.1.2.	Waste codes/waste designat	ions according to Law.		
	140 IIIIOIIIIAUOII AVAIIADIE			
13.1.3.	Waste codes/waste designat	ions according to Low:		
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances			
	i			
13.1.4.	Sewage disposal – relevant i	nformation:		
	Waste must not be disposed	of into the sewage system.		
13.1.5.	Other disposal recommenda	tions:		
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collect authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Subthe packaging to the collectors authorized by the ministry in charge. Do not dispose of in places will ignition may occur.			
13.1.6.	Relevant Community provisions:			
	Disposal must be made acco	rding to official regulations.		
SECTION	N 14. Transport information			
	Transporting/shipment by road	d (ADR)		
UN num	ber:	1230		
······································	er shipping name:	Methanol		
······································	rt hazard class(es):	3 (6.1)		
Packing - ·	-			
	nental hazards:			
Special p	precautions for user:	-		



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

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: -	

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

	Authorisations and/or rest	crictions 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 and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 199 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessmen	nt
	None	

SECTIO	N 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 R	EAGENT		
Product code: BD1-OT-X** Date of c		Date of compilation:	03.04.2023.	Version:	6

16.3.		literature references source of data:	-
16.4.	Classification and procedure 1272/2008 (CLP)		used to derive the classification for mixture according to Regulation (EC)
Classific	catior	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.	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-manus according to obtain a Observation and a factor according to	
ANNEX: Exposure scenario resulting to Chemical safety assessment	
-	



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

SECTI	ON 1: Identification of	the substanc	e/mixture a	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	BIO-DIFF 2	BIO-DIFF 2 REAGENT		
	Chemical name:	-	-		
	Catalogue number:	BD2-OT-X*	BD2-OT-X**		
1.2.	Relevant identified us	es of the subs	stance or mi	xture 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	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:	В	BioGnost Ltd.		
	Address:	N	Medjugorska 59, Zagreb +385 1 2409997		
	Telephone number:	+			
	Fax no.:	+	+385 1 2404039 <u>msds@biognost.hr</u>		
	e-mail of competent p	oerson: <u>m</u>			
	National contact:	-			
	Emergency telephone	number			
1.4.	=mergeney terephone				
1.4.	National Protection ar	nd Rescue Dir	ectorate:	112	
1.4.	3 , .	nd Rescue Dir	ectorate:	112 +385 1 2348 342	

SECTIO	ON 2. Hazards identification						
2.1.	Classification of the substance or mixture						
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)						
	Hazard class and categor	y code:	Hazard statements*:				
	Not identified as hazardous subs	stance.	-				
2.1.2.	. Additional information						
	-						
*For fu	ll text of Hazard- and EU Hazard-st	tatements: see S	ection 16				
2.2.	Label elements						
	Product identification:	BIO-DIFF 2 R	EAGENT				
	Identification number:	-					
	Authorization no.:	-					
	Hazard pictograms: -						



No known endocrine disrupting properties.

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

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Trading name: Product code:		BIO-DIFF 2 REAGENT							
		BD2-OT-X**	Date of compilation:	14 November 2022	Version:	: 4			
•••••									
Signal word:		-							
	Hazard statements: Precautionary statements: Supplemetal hazard information (EU):		-						
			-						
			on _						
2.3.	Other ha	zards							
	Endocrine	e Disrupting Properties:							

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

SECTI	ON 4. First aid measures					
4.1.	Description of first aid measu	ures				
	General notes:	-				
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.				
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.				
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.				
	Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.				
	Self-protection of the first ai	der: Treat symptomatically.				
4.2.	Most important symptoms a	Most important symptoms and effects, both acute and delayed				
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.				
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.				
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.				



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

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

SECTIO	SECTION 6. Accidental release measures						
6.1.	Personal precautions, protective equipment and emergency procedures						
6.1.1.	For non-emergency 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. 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:	and 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 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 ightly 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 lirectly leads into sewage system. Secure proper rentilation.				
	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)

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	2 REAGENT	•		
Product code:	BD2-01	Γ-X**	Date	of cor	mpilation:	14 Novem	ber 2022	Version: 4
Recomme	endations:				_			
		cific solution	uc.		_			
maastiai	sector spe	cinc solution	13.					
SECTION 8. Expos	ure contr	ols/persona	al protec	tion				
8.1. Control p		0.0, pc. 50.110	р. о сес					
				Occi	upational e	xposure limit		
Substance	<u> </u>	CAS I	Vo	values/short term values		Biolog	gical limit values	
					ppm	mg/m³		
-		-			-	-	No informa	tion available
ı								
Substance - name:								
EC No: -		CAS No:	-					
DNEL			,					
				Inc	dustrial			
D (Acute	cute Acut		e	Chron	ic	Chronic
Route of exposure	effe	ect local effec		ct sys	systemic effec		ocal	effect systemic
Oral	-							
Inhalation	-		-		-		-	
Dermal	-		-			-	-	
Critical physical pa	rameters:	solubility, fla	mmabilit	ty, cor	rosivity:	-		
			ı	Co	nsumer			
Route of exposure		Acute				Chron		Chronic
•	effe	ect local	effe	ect sys	temic	effect lo	ocal	effect systemic
Oral	-		-			-		
Inhalation	-		-			-	-	
Dermal	-		-			-	-	
PNEC								
Environmental protection target				PNEC				
Fresh water					nation availab			
Freshwater sediments				No information available				
Marine water					No information available			
Marine sediments					No information available			
Food chain					No information available			
Microorganisms in sewage treatment				No information available				

No information available



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

Air			No information available				
8.2.	Exposure controls						
8.2.1.	Appropriate engineering controls						
	Substance/mixture relate measures to prevent expoduring 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 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 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						
			ctive gloves must be according to the EU Directive 2016/425/EEC and ard EN 374.				
	Hand protection:		Glove material: nitrile rubber				
		Glove thickness: ≥0.50 mm Break through time: >480 min					
	Other skin protection:		rantistatic 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:	filter f	ective full face mask (EN 136) or half mask (EN 140) equipped with a for organic vapors, type "A" (boiling point >65°C) acording to EN 7) used when concentration levels exceed GVI.				
8.2.2.4.	Thermal hazards:	No inf	nformation available				
8.2.3.	Environmental exposure	controls	5				
	Substance/mixture relate measures to prevent expe		See Section 6				
	Structural measures to pr exposure:	event	Use modern equipment.				
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.				
	Technical measures to 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
pH:	5.5 – 6.5	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available

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

Acute toxici	ty:							
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure	time	Results		
Oral exposure:	No information available	-	LD ₅₀	-		-		
Dermal exposure:	No information available	-	LD ₅₀	-		_		
Inhalation exposure:	No information available	-	LC ₅₀	_		-		
Specific targ	get organ toxicity – si	ngle exposure ((STOT SE):					
	Specifi	c effects	Target	organ		Note		
Oral exposure:	No information a	available	No information	on available	-			
Dermal exposure:	No information a	available	No information available -					
Inhalation exposure:	No information a	available	No information available -					
Aspiration h	nazard:	No info	rmation available					
·								
Irritation an	d corrosion:							
	Exposure time	Species	Evaluation	Method		Note		
Skin irritation:	-	rabbit	-					
Eye irritation:	-	rabbit	-					
Sensitization	n							
Dermal exposure:	No information availa	able				_		
Inhalation exposure:	No information availa	able						
Ē.								
Symptoms i	elated to the physica	l, chemical and	toxicological chara	cteristics				
Oral exposure:	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.							
Dermal exposure:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.							



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

innalation expositre:			large amounts eezing, heada			dequately vent	ilated perime [.]	ter may cause
Eye exposure:		Direct eye co ensation.	ontact may cause slight to moderate irritation, lacrimation and burning					
Repeate	ed dose	toxicity (sub	acute, subchro	onic, chronic	c)			
Породо		Dose	Exposure time	Species		Method	Evaluation	Note
Subacute oral	No ir availat	nformation ble	No information available	No informatio available	on	No information available	No information available	۱ -
Subacute dermal	No ir availat	nformation ble	No information available	No informatio available	on	No information available	No informatior available	۱ -
Subacute inhalation	No ir availak	nformation ble	No information available	No informatic available	on	No information available	No informatior available	- ١
Subchronic oral	No ir availat	nformation ble	No information available	No informatio available	on	No information available	No informatior available	۱ -
Subchronic dermal	No ir availat	nformation ble	No information available	No informatio available	on	No information available	No informatior available	۱ -
Subchronic inhalation	No ir availat	nformation ble	No information available	No informatio available	on	No information available	No information available	۱ -
Chronic oral	No ir availat	nformation ble	No information available	No informatio available		No information available	No information available	۱ -
Chronic dermal	No ir availat	nformation ble	No information available	No informatio available	on	No information available	No information available	۱ -
Chronic inhalation	No ir availak	nformation ble	No information available	No informatic available		No information available	No informatior available	า -
Specific	target	rgan tovicit	y – repeated e	vnosuro (CT		:)·		
Specific	taryet C		pecific effects	7h03016 (31	OT NE		an	Note
Subacute oral			tion available		Target organ No information available -		-	
Subacute dermal			tion available			formation avai		_
Subacute inhalat			tion available			formation avai		_



toxicity

SAFETY DATA SHEET 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				
	:	,					

Subchro	onic oral	No informat	tion available	No information available	-			
Subchro	onic dermal	No informat	tion available	No information available	-			
Subchro	onic inhalation	No informat	tion available	No information available	-			
Chronic	oral	No informat	tion available	No information available	-			
Chronic	dermal	No informat	tion available	No information available	-			
Chronic	inhalation	No informat	tion available	No information available	-			
	CMR effects (c	arcinogenicity	; mutagenicity; rep	oductive toxicity)				
	Carcinogenicit	y:	Current studies	Current studies on test animals did not indicate carcinogenic effects.				
	Mutagenicity i	n-vitro:	Current in vitro tests did not indicate mutagenic effects.					
	Genotoxicity:		No information	No information available				
	Mutagenicity i	n-vivo:	Current in vivo tests did not indicate mutagenic effects.					
	Germ cell mut	agenicity:	No information	No information available				
	Reproductive t	toxicity:	No toxicity on reproductive organs was determined in reproductive organs.					
	Summary of ev	valuation of th	e CMR properties:	-				
11.2.	Information on other hazards:							
11.2.1.	Endocrine disr	upting proper	ties:					
	No known end	No known endocrine disrupting properties that affect human health.						
11.2.2.	Other informa	tions:						

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

time



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

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

12.2. Persi	istence and degradability			
Abio	tic 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. Bi	12.3. Bioaccumulative potential								
0	ctanol-water partition	coefficient	(log Ko	ow)					
Value	Concentration	рН	°C	Method	Evaluation	Note			
-	No information available	-	-	No information available	No information available	-			
i	Bioconcentration factor (BCF)								
Valu	ie Spec	ies		Method	Evaluation	Note			



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Trading	name:	BIO-DIFF ?					2 REAGENT						
Product	code:	BD2-0	OT-X**	Date of compilation			ation:	14 November 2022 Version			rsion:	4	
No inforn available	nation	No availab	inform	ation	ation No information available		No info	ormation le		No info availabl		n	
1													
(Chronic ec	otoxicit	y										
	Value		Dose		osure ime	Spe	ecies	Met	hod	Eva	luation		Note
Chronic to	oxicity on	fish	LC ₅₀	No infor	mation	No inforr availa	nation ble	No informa availab		No inforr availa	mation Ible	-	
Chronic toxicity on crustacea (<i>Daphnia</i>)		EC ₅₀	No infor availa	mation	No inforr availa	nation ble	No informa availab						
12.4. N	Mobility in	soil											
	•		ed distributi	on in e	environme	ntal c	ompart	ments:					
١	No informa	ation av	ailable										
9	Surface ter	nsion:											
	Value		°C	Concentration		Method			Note				
i	No nformatio available		ormation ailable	No information No infavailable available		formation - ble -							
A	Adsorption	n / deso	rption								2		
Transport	•	/D coef enry's co		lc	og Kow	Ev	aporati	on rate	Method			No	ote
Soil-wate	r No availa		formation	No ir availa	nformatior able		inform ailable	nation		No information -			
Water-air	No availa		formation	No information available			inform ailable	nation	No info availabl		on -		
Soil-air No information available No information available				o inform ailable	nation	No info availabl		on -					
	Results of I			ssment									



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

12.6.	Endocrine disrupting properties				
	No known endocrine disrupting properties that affect the environment.				
12.7.	Other adverse effects				
	No adverse effects are expected.				
SECTIO	l 13. Disposal considerations				
13.1.	Waste treatment methods				
13.1.1.	Product/Packaging disposal:				
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.				
13.1.2.	Waste codes/waste designations according to Law:				
	No information available				
13.1.3.	Waste treatment – relevant information:				
	No information available				
13.1.4.	Sewage disposal – relevant information:				
	Waste must not be disposed of into the sewage system.				
40.4 5					
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	l 14. Transport information				
	Transporting/shipment by road (ADR)				
UN num	ber: Not subject to transport regulations.				
UN prop	er shipping name: -				
Transpo	t hazard class(es): -				



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Trading name:	Trading name: BIO-DIFF 2 REAGENT					
Product code:	BD2-OT-X**	Date of compilation:	14 November 2022	Version: 4		
İ			-	. 1		
Packing group:		-				
Environmentally haz	ardous:	-				
Special precautions	for user:	-				
Transportin	g/shipment by rai	il (RID)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	name:	-				
Transport hazard cla	ıss(es):	-				
Packing group:		-				
Environmentally haz	ardous:	-				
Special precautions	for user:	-				
Inland wate	erway transport (A	DN)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	name:	-				
Transport hazard cla	ıss(es):	-				
Packing group:		-				
Environmentally haz	ardous:	-				
Special precautions	for user:	-				
Transportin	g/shipment by sea	a (IMDG)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	name:	-				
Transport hazard cla	ıss(es):	-				
Packing group:		-				
Environmentally haz	ardous:	-				
Special precautions	for user:	-				
Transportin	g/shipment by air	· (ICAO-TI/IATA-DGR)				
UN number:		Not subject to transport regulations.				
UN proper shipping	name:	-				
Transport hazard cla	ıss(es):	-				
Packing group:		-				
Environmentally haz	ardous:	-				
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 enviror	nmental regulations/legislation specific for the substance or mixture					
	EU regulations						
	Authorization and/or rest	rictions of use					
***************************************	Authorizations:	-					
	Restrictions:	-					
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);					
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-					
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act					
15.2.	Chemical safety assessme	ent					
	None						

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 ₅₀	Lethal dose, 50%			
		LC ₅₀	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.	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:	-		
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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Trading name:	BIO-DIFF 3 REAGENT			
Product code:	BD3-OT-X**	Date of compilation:	14 November 2022	Version: 6

SECTI	ON 1: Identification of	the substanc	e/mixture a	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	BIO-DIFF 3 REAGENT			
	Chemical name:	-			
	Catalogue number:	BD3-OT-X*	*		
1.2.	Relevant identified uses of the substance or mixture and uses advised against				
	Uses: Uses advised against: Reason why uses advised against		Buffered blue component of Bio-Diff kit.		
			Only the identified uses are advised.		
			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: B		lioGnost Ltd.		
	Address: Telephone number: Fax no.:		Medjugorska 59, Zagreb		
			+385 1 2409997 +385 1 2404039		
	e-mail of competent person: r		msds@biognost.hr		
	National contact:		-		
1.4.	Emergency telephone number				
	National Protection and Rescue Dire		ectorate:	112	
	Medical information:			+385 1 2348 342	

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 subs	stance.	-	
2.1.2.	Additional information			
	-			
*For fu	ll text of Hazard- and EU Hazard-s	tatements: see S	ection 16	
2.2.	Label elements			
	Product identification:	BIO-DIFF 3 R	EAGENT	
	Identification number:	-		
	Authorization no.:	-		
	Hazard pictograms:	-		



Endocrine Disrupting Properties:

No known endocrine disrupting properties.

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Trading name:		BIO-DIFF 3 REAGENT						
Product code: BD3-OT-X**		Date of compilation:	14 November 2022	Version: 6				
Signal v	vord:	-						
	statements:	-						
Precaut	ionary statements:	-						
Suppler (EU):	netal hazard information	-						
2.3. Other h	azards							

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

SECTIO	SECTION 4. First aid measures								
4.1.	Description of first aid measu	res							
	General notes:	-							
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.							
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.							
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.							
	Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.							
	Self-protection of the first ai	ler: Treat symptomatically.							
4.2.	Most important symptoms a	nd effects, both acute and delayed							
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.							
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. 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					
	-					

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

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 personne members without protective equipment. Remove a 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 con	tainment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.				



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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.				
6.3.3.	Other information:	-				
6.4.	Reference to other 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 not 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:	venti	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:	Manı	ufacturer's original packaging.				
	Requirements for storage rooms and vessels:		away from food and drink. Keep the containers ly closed.				
	Advices for storage equipment:	be re	storage must be made of hard material; floors must esistant to chemicals. There must be no drain that etly leads into sewage system. Secure proper flation.				
	Further information on storage conditions:	and o	ot place the unused material in the storage room do not use empty containers for storing other nicals. Do not store with incompatible materials (see on 9).				
7.3.	Specific end use(s)						



Soil (agricultural)

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Trading name:		BIO-DIFF 3 REAGENT							
Product code: BD3-OT		T-X** Date of con		of compilation	mpilation: 14 November		Version: 6		
Recommer	ndations:			_					
Industrial s	ector spe	cific solution	ns:	-					
				<u> </u>					
SECTION 8. Exposu	ıre contr	ols/persona	al protec	tion					
8.1. Control pa	rameters								
Substance		CAS I	Vo	Occupational values/short		Biolog	Biological limit values		
				ppm	ppm mg/m³				
-		-		-	-	No informat	tion available		
Substance - name:									
EC No: -		CAS No:	-						
DNEL									
				Industrial					
Route of exposure:		Acute Acute		Acute	Chronic		Chronic		
effe		ect local effect s		ect systemic	effect local		effect systemic		
Oral	-		-		-				
Inhalation	-		-						
Dermal	-		-		_				
Critical physical para	ameters:	solubility, fla	ımmabili	ty, corrosivity:	-				
			1	Consumer	1				
Route of exposure:		Acute	Acute		Chronic		Chronic		
-	effe	ect local	effe	ect systemic	effect lo	ocal	effect systemic		
Oral	-		-		-	-			
Inhalation	-		-		-	-			
Dermal	-		-		-	-			
PNEC				T					
Environmental protection target					PNEC				
Fresh water					No information available				
Freshwater sediments					mation availabl				
Marine water					No information available				
Marine sediments					No information available				
Food chain					No information available				
Microorganisms in sewage treatment				No infor	No information available				

No information available



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

Air			No information available				
8.2.	Exposure controls						
8.2.1.	Appropriate engineering	controls	5				
	Substance/mixture relate measures to prevent exp during identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.				
	Structural measures to preserve:	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 prexposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.				
8.2.2.	Personal protection equi	pment					
8.2.2.1.	Eye and face protection:		Safety glasses that stick to face (preventing splashing) (EN 166) or visor.				
8.2.2.2.	Skin protection						
8.2.2.2.	Hand protection:		ctive gloves must be according to the EU Directive 2016/425/EEC and ard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min				
	Other skin protection:		ear antistatic clothing made of natural fibers (such as cotton) with long evees (EN 13034), and shoes that cover the entire foot (EN 10335).				
8.2.2.3.	Respiratory protection:	filter f	ctive full face mask (EN 136) or half mask (EN 140) equipped with a for organic vapors, type "A" (boiling point >65°C) acording to EN 7) used when concentration levels exceed GVI.				
8.2.2.4.	Thermal hazards:	No in	formation available				
8.2.3.	Environmental exposure	controls					
	Substance/mixture relate measures to prevent exp		See Section 6				
	Structural measures to preserve:	revent	Use modern equipment.				
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.				
	Technical measures to prexposure:	event	See Section 6				

SECTION 9. Physical and chemical properties



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Trading n	ame:		BIO-DIFF	3 REAGENT	
Product c	ode: l	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
рН:	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			,			
Route of exposure: Method		Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure t	ime	Results	
Oral exposure:	No information available	_	LD ₅₀	-		_	
Dermal exposure:	No information available	-	LD ₅₀	-		-	
Inhalation exposure:	No information available	-	LC ₅₀	-		-	
Specific ta	rget organ toxicity – sir		-		1		
		effects		organ		Note	
Oral exposure:	No information a	vailable	No information	on available	-		
Dermal exposure:	No information a	vailable	No information	on available	-		
Inhalation exposure	: No information a	vailable 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	n e						
Dermal exposure:	No information availa	ahla					
Inhalation	No information availa						
exposure:							
Symptoms	related to the physical	chemical and	toxicological chara	octoristics			
Symptoms	Swallowing may ca				no mourt	h hurning	
Oral exposure:	sensation; higher le ln case of vomiting concentration may	evels of concen g, aspiration cau	ntration may cause uses coughing, diff	nausea, abdor	ninal pa	in and vomiting.	



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Trading n	ame:		BIO-DIFF	3 REAGENT	
Product c	ode: l	BD3-OT-X**	Date of compilation:	14 November 2022	Version: 6

innalation exposition		nhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.								
Eye exposure: Direct eye co sensation.			contact may cause slight to moderate irritation, lacrimation and burning							
Reneate	nd dos	e toxicity (sub	acute, subchro	onic chroni	(c)					
Керейс		Dose Dose	Exposure time	Species	<u>C)</u>	Method	Evaluation	Note		
Subacute oral	Subacute oral No information available		No information available	No informati available	on	No information available	No informatio available	on -		
Subacute dermal	No avail	information able	No No No No Information information available available available		informatio	n -				
Subacute inhalation	No avail	information able	No information available	No information available		No information available	No informatio available	n -		
Subchronic oral	onic oral No information available		No information available	No informati available	on	No information available	No informatio available	n -		
Subchronic dermal	No avail	information able	No information available			No information available	No informatio available	n -		
Subchronic inhalation	No avail	information able	No information available	No information available		No information available	No informatio available	n -		
Chronic oral	No avail	information able	No information available	No information available		No information available	No informatio available	on -		
Chronic dermal	No avail	information able	No information available	No informati available	on	No information available	No informatio available	on -		
Chronic inhalation			No information available	No informati available	on	No information available	No informatio available	on -		
Chasiti-	tarcat	organ tavisit	v ropostad -	vnocure (C	TOT P)E).				
Specific	target	1	y – repeated e pecific effects	xposure (S	IOIR	Target orga	an	Note		
Subacute oral			tion available		No i	nformation avai		-		
Subacute dermal			tion available			nformation avai		-		
Subacute inhalat			tion available			nformation avai		_		



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Trading name:		BIO-DIFF	3 REAGENT	
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Subchro	onic oral	No informati	on available	No information available	-				
Subchro	onic dermal	No informati	on available	No information available	-				
Subchro	onic inhalation	No informati	on available	No information available	-				
Chronic	nronic oral No information		on available	No information available	-				
Chronic	Chronic dermal No information		on available	No information available	-				
Chronic inhalation No informatio		on available	No information available	-					
	CMR effects (c	arcinogenicity;	mutagenicity; repr	oductive toxicity)					
	Carcinogenicity:		Current studies	Current studies on test animals did not indicate carcinogenic effects.					
	Mutagenicity in-vitro:		Current in vitr	Current in vitro tests did not indicate mutagenic effects.					
	Genotoxicity:		No information	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 or organs.	No toxicity on reproductive organs was determined in reproductive organs.					
	Summary of ev	valuation of the	e CMR properties:	-					
11.2.	Information or	n other hazards	:						
11.2.1.	Endocrine disr	upting propert	ies:						
	No known end	locrine disrupti	ng properties that	affect human health.					
11.2.2.	Other informa	tions:							

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



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Trading nam	ie:				BIO-DIFF	3 R	EAGENT			
Product code: BD3-OT-X**		Dat	Date of compilation: 14 November 2			r 2022 Version		n: 6		
Fish		LC ₅₀	96 hours		No information available	_	information ilable	No informatio available	information -	
Crustacea:		EC ₅₀	48 hours		No information available	No information available		No informatio available	on -	
Algae/aquatic plants		IC ₅₀	72 hours		No information available		information ilable	No informatio available	on -	
Other organisms			-	-		-	-			
	tic degra	adation	ollity	-						
<u> </u>	Deg	radation half	f-lives	Method			Evaluation			Note
Marine water	No inf	formation ava	ailable	No information availab		ble	No informa	tion availab	le	-
Fresh water	No inf	formation ava	ailable	No information availab		ble	ble No information availab		le	-
Air	No inf	formation ava	ailable	No information availab		ble	ble No information availab		le	-
Soil	No inf	formation ava	ailable	No	information availa	ble	No informa	tion availab	le	-
Biod	egradati	on								
% Degradation Time (days))		Method		Evaluation		No	te	
No information No available av			rmation No						information ailable	

/alue	tanol-water partition Concentration	рН	°C	Method	Evaluation	Note
	No information available	-	-	No information available	No information available	-



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_	rading name: BIO-DIFF 3 REAGENT											
Product cod	de: BI	D3-OT-X**	D	Date of compilation:		14 November 2022		٧	Version: 6			
No informati available	_	No information		ntion No information available		No information available		1	No information available		n	
	•											
	onic ecoto	Dose		oosure ime	Speci	es	Met	hod	Eva	luation		Note
Chronic toxic	city on fish	1 LC ₅₀	No N information in		No nforma availabl		No informa availab		No inforn availa		-	
Chronic toxic crustacea (<i>De</i>	-	EC ₅₀	No infor availa	mation i	No nforma availabl		No informa availab					
No info	Surface tension: Value °C No No information information available available				Method No information available		-	Note				
Ads	orption / (desorption						ī				
Transport		coefficient /'s constant	lc	og Kow	Eva	ooratio	on rate	Method			No	ote
Soil-water	No available	information	No ir availa	nformation able		nform able	ation	No information available		on -		
Nater-air No information No information			-			nform able	ation	No info	ormatio ole	n -		
Water-air	Soil-air No information available				No i	No information available		No information available				



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

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	ccording to Law:	
	No information available		
	-		
13.1.3.	Waste treatment – relevant informa	ition:	
	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:		
	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 ha	zardous:	-						
Special precautions	for user:	-						
Transporti	ng/shipment by rail	(RID)						
UN number:		Not subject to transport regulations.						
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	for user:	-						
Inland wat	erway transport (A[DN)						
UN number:		Not subject to transport regulations.						
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	for user:	-						
Transporti	ng/shipment by sea	a (IMDG)						
UN number:		Not subject to transport regulations.						
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	for user:	-						
Transporti	ng/shipment by air	(ICAO-TI/IATA-DGR)						
UN number:		Not subject to transport regulations.						
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	for user:	-						

The product is not subject to classification.

Further information:



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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	nmental regulations/legislation specific for the substance or mixture			
	EU regulations				
	Authorization and/or rest	rictions of use			
	Authorizations:	-			
	Restrictions:	-			
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);			
	Information according 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	ON 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 ₅₀	Lethal dose, 50%
		LC ₅₀	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				
Product code:	BD3-OT-X**	Date of compilation: 14 November 2022	Version: 6		

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
Classification		Classification procedure			
_		-			
16.5.	16.5. Relevant H statements (number 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



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	UTION, pH 6.8			
	Chemical name:	-					
	Catalogue number:	PUF68-OT-	X**				
1.2	Relevant identified uses of the substance			nixture and uses advised against			
	Uses: Uses advised against:		Buffer so	olution for use in hematology, 6 mM.			
			Only the	e identified uses are advised.			
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.				
1.3	Details of the supplier of the safety data sheet						
	Supplier:		BioGnost Ltd.				
	Address:	Address:		Medjugorska 59, Zagreb			
	Telephone number:		+385 1 2409997				
	Telefax.:		+385 1 2404039				
	e-mail of competent p	erson:	msds@biognost.hr				
	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 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: -					
	Authorization number: -					
	Hazard pictograms:	-				



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

	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	Endocrine Disrupting Prope	rties:
	No known endocrine disrupti	ng properties
	Results of PBT and vPvB ass 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	SECTION 4. First aid measures				
4.1	Description of first aid measures				
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.			
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.			
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.			
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.			
	Self-protection of the first aider:	-			
4.2	Most important symptoms and effects, both acute and delayed				
	Following inhalation:	No information available.			
	Following skin contact:	No information available.			
	Following eye contact:	No information available.			



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Trading name:	BUFFER SOLUTION, pH 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	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 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	SECTION 6. Accidental release measures				
6.1	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.			
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:				
	Use protective equipment; in 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, pH 6.8				
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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. Th	oroughly was	sh hands after work and before eating.	
7.2	Conditions for safe storage, including any incom	patibilities		
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in well ventilated storage roomsat temperatures rangifrom 15 to 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:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no dr that directly leads into sewage system. Secure proportion.		
	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 10).		
7.3	Specific end use(s)			
	Recommendations:	-		
	Industrial sector specific solutions:	_		

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



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Trading name	2:	BUFFER SOLUTION, pH 6.8										
Product code:		PUF68-0	OT-X**		Date	of c	ompila	tion:	22 [Dec 2022	Version:	4
	·								•			
-				-		-		-			-	
Substance nam	ie:	-	1				<u> </u>					
EC No:		-	CAS No):	-							
DNEL												
				1	li	ndus	strial			1		
Route of		Acu			Acute	Chronic				Chronic		
exposure:		effect	local	effec	t system	nic effect local			effect systemic			
Oral	- -			-			-			-		
Inhalation	-			-			-			-		
Dermal				-			-			-		
Critical physica	l parar	meters: s	solubility,	flamma								
		T		1		onsi	umer					
Route of			Acute			Chronic			Chronic			
exposure:	-		effect systemic		nic	effect local			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					No information available						
Food chain						No information available						
Microorganism		ewage tr	eatment			No information available						
Soil (agricultura	al)					No information available						
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, pH 6.8							
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4				

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

SECTI	ON 9. Physical and chemical prope	erties	
9.1	Information on basic physical and	chemical properties	
		Value	Method
	Physical state:	liquid	No information available
	Color:	colourless	No information available
	Odour/odour threshold:	no odor/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available



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Trading name:		BUFFER SOLUTION, pH 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		
	-		

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

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008									
Acute to	oxicity:								
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	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 informa available		-	
Subacute dermal	No avai	information ilable	No information available	No information available	No infor availa	mation able	No informa available			

No

information

available

No information

available

Subacute

inhalation

No

information

available

No

information

available

No

information

available



Reproductive toxicity:

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Trading name:		BUFFER SOLUTION, pH 6.8						
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r roduct code.	10	100-01-7	De	ate of compila	tion.	22 Det	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 availa	information able	No information available	No information available	No infori availa	mation able	No information available	on	-	
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 information available			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 int	formation	n available	-		
Subacute derma		No informa	ation available		No in	formation	n available	-		
Subacute inhalat	tion	No informa	ntion available		No information available No information available		-	-		
Subchronic oral		No informa	ntion available				-			
Subchronic dern	nal	No informa	ntion available		No information available		-			
Subchronic inha	lation	No informa	ntion available		No information available		-			
Chronic oral			ntion available		No information available		-			
Chronic dermal			ntion available		No information available		-			
Chronic inhalation	on	No informa	ntion available		No in	formation	n available	-		
			y; mutagenicity	y; reproductive						
Carcino				No inform						
Mutage		n vitro:		No inform						
Genoto	<u>-</u>	•		No inform						
Mutage				No inform						
Germ c	eli muta	agenicity:		No inform	ation av	allable				

No information available



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Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4			

	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 informations:
	-

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

12.2 Persistence and degradability



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Trading name:		N, pH 6.8			
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Abioti	c degr	adation									
	D	egradation h	alf-liv	es	N	Method		Evaluatio	n		Note
Marine water	arine water No information available		No information available		No information available		-				
Fresh water	Noi	information a	availak	ole	No inf availal	ormation ole	No ii avail	nformatio able	n	-	
Air	Noi	information a	availab	ole	No inf availal	ormation ole	No ii avail	nformatio able	n	-	
Soil	Noi	information a	availab	ole	No inf availal	ormation ole	No ii avail	nformatio able	n	-	
Biode	aradat	ion									
% Degradati		Time (davs)		N	Method		Evaluatio	n		Note
No information			nforma	ition		formation	No ii	nformatio		No info	rmation
	ol-wat	etive potentia er partition of entration		- 1	log Kow	/) Method		Evalu	ation		Note
			-		-	_		_		-	
Biocor	ncentra	ation factor (BCF)								
Value		Speci	es			Method		Evaluati	on		Note
No information No available availab		No in available	forma	tion	No inf	ormation ole	No information available		-		
Chron	ic eco	toxicity					i			•	
Value		Do	se	•	osure ime	Species	N	/lethod	Evalu	uation	Note
		sh LC ₅₀		No	mation	No information	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	Date of compilation:		22 Dec 2022		Version:	4
Chronic toxicity on crustacea (<i>Daphnia</i>)		EC ₅₀	No information available	tion information		No No information available available		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	od		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 information No in		rmation	ation No information available			
Water-ai	No	information	No informatio	available n No info	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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Trading name:		BUFFER SOLUTION	l, pH 6.8		
Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

13.1.1.	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.	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:			
	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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Product code:	PUF68-OT-X**	Date of compilation:	22 Dec 2022	Version:	4

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

SECTI	ON 1: Identification of	the substance	e/mixture	and of the company/undertaking	
1.1	Product identifier	Product identifier			
	Trading name:	BUFFER SO	LUTION, p	H 7.2	
	Chemical name:	-			
	Catalogue number:	PUF72-OT-X	X**		
1.2	1.2 Relevant identified uses of the substance or mixture and uses advised against			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 advis	sed against:	device, r	duct is intended for use only as an <i>in vitro</i> diagnostic medical registered at the Agency for Medicinal Products and Medical and there is no reason to use it for other purposes.	
1.3	Details of the supplier	of the safety	data shee	t	
	Supplier:	Supplier:		BioGnost Ltd.	
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent p	erson:	msds@biognost.hr		
	National contact:		-		
1.4	Emergency telephone	Emergency telephone number			
	National Protection ar	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	CTION 2. Hazards identification						
2.1	Classification of the substance	Classification of the substance or mixture					
2.1.1	Classification according to Reg	gulation (EC) No 1	272/2008 (CLP)				
	Hazard class and categ	ory code:	Hazard statements*:				
	Not identified as hazardous su	bstance.	-				
2.1.2.	Additional information						
	-						
*For fu	ll text of Hazard- and EU Hazard	-statements: see S	ECTION 16				
2.2	Label elements						
	Product identification:	BUFFER SOLUTI	ON, pH 7.2				
	Identification number:	Identification number: -					
	Authorization number: -						
	Hazard pictograms:	-					



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

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

SECTION 3. Cor	SECTION 3. Composition/information on ingredients							
CAS/ EC/ Index number	REACH Registration No	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 effects, both acute and delayed	
	Following inhalation:	No information available.
	Following skin contact:	No information available.
	Following eye contact:	No information available.



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

SECTION 5. Firefighting measures						
5.1	Extinguishing media	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	ubstance or mixture				
	Hazardous combustion products:	No information available.				
5.3	Advice for firefighters					
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.					
5.4	Additional information					
	Do not contaminate the environm	ent with extinguishing media.				

SECTION 6. Accidental release measures							
6.1	Personal precautions, protective equipment and emergency procedures						
6.1.1.	For non-emergency personnel						
	Protective equipment: Use personal protective equipment (see Section 8).						
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.					
	Emergency procedures:	Mark the area using proper signs.					
6.1.2.	For emergency responders:						
	Use protective equipment; in 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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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	SECTION 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. Th	oroughly was	sh hands after work and before eating.					
7.2	Conditions for safe storage, including any incompatibilities							
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage roomsat temperatures ranging from 15 to 25 °C.						
	Packaging materials:	Manufactu	Manufacturer's original packaging.					
	Requirements for storage rooms and vessels:		ep away from food and drink. Keep the containers					
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no dra that directly leads into sewage system. Secure proper ventilation.						
	Further information on storage conditions:	Do not place the unused material in the storage roo and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).						
7.3	Specific end use(s)							
	Recommendations:	-						
	Industrial sector specific solutions:	_						

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



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Product code: PUF72-OT-X**			Date of compilation: 22 Dec 2022			Dec 2022	Version:	4				
										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			cute		Acute			Chro			Chronic	
exposure:		effec	t local	effect systemic		mic	c 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)						N	No information available					
Air				N	No information available							
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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Trading name:	BUFFER SOLUTION, pH 7.2					
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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 exposure:		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 modern equipment.				
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the lace.			
	Technical measures to prevent exposure:	See 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, pH 7.2					
Product code:	PUF72-OT-X**	Date of compilation:	22 Dec 2022	Version:	4	

	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	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 ₅₀ /LC ₅₀ or ATE _{mix}	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	-			
Dermal:	١	lo information	available	No in	formation a	available	-		
Inhalation: No information available			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. ²
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 information available	No information available	No information available		No information available	on	-
Chronic oral	Chronic oral No information available		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	ation available		No information available			-	
Subacute derma		No informa	ation available		No in	formatio	n available	-	
Subacute inhalat	ion	No informa	ition available		No information available		-		
Subchronic oral		No informa	ation available		No information available		-		
Subchronic dern	nal	No informa	ation available		No information available		-		
Subchronic inha	lation		ation available		No information available		-		
Chronic oral			ation available		-		n available	-	
Chronic dermal			ation available		No information available		-		
Chronic inhalation	on	No informa	ation available		No in	formatio	n available	-	
			y; mutagenicity	y; reproductive					
Carcino				No inform					
Mutage	·····	n vitro:		No inform					
Genoto				No inform					
Mutage				No inform					
Germ co	Germ cell mutagenicity:			No inform	iation av	/allable			

No information available



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

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

12.2 Persistence and degradability



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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 information available		No information available		-	
Fresh water	No	informatio	mation available		No information available		No information available		-	
Air	No	No information available		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		availabl	e
		ative poter		: -: - · · · · ·	la a Kan					
	ol-wat Conc	ative poter ter partition		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	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		
Produc	t code:	PUF72-OT-X**	Date o	f compilati	on:	22 De	c 2022	Version:	4
Chronic toxicity on crustacea (<i>Daphnia</i>)		No No No information information available available available			No information 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	Evaporati	on 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	rmation No information No information available available		nation	n No information available		-	
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	al:				
	Submit for disposal to the Protection.	legal person authorized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste design	ations according to Law:				
	Packaging that contains re	sidual hazardous substances or is contaminated with hazardous substances				
13.1.3.	Waste treatment – relevan	t information:				
	No information available					
13.1.4.	Sewage disposal – relevan					
	Waste must not be dispos	ed of into the sewage system.				
13.1.5.	Other disposal recommen	dations:				
	authorized by the ministry	duct's remains into the sewage system. Submit the remains to the collectors in charge. Do not dispose of the packaging into the sewage system. Submit ctors authorized by the ministry in charge.				
13.1.6.	Relevant Community prov	isions:				
	-					
SECTIO	N 14 TRANSPORT INFORM	ATION				
	Transporting/shipment by ro	pad (ADR)				
UN num	ber:	Not subject to transport regulations				
UN prop	er shipping name:	-				
Transpo	rt hazard class(es):	-				
Packing	group:	-				
Environr	mentally hazardous:	-				
Special p	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: -	

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	nt
	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 (number 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					
-					