

BIO-DIFF RTU KIT

The kit contains:

Bio-Diff 1 RTU reagent

Bio-Diff 2 RTU reagent

Bio-Diff 3 RTU reagent

Buffer tablet, pH 6.8

Buffer tablet, pH 7.2



Page 1 of 18

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

1.1.	Product identifier			
	Trade name:	BIO-DIFF 1 RT	U REAGENT	
	Chemical name:	-		
	Catalogue number:	BD1-RTU		
1.2.	Relevant identified uses of the	substance or mix	ture and uses advised against	
	Uses:	Fixative comp	onent of Bio-Diff RTU kit.	
	Uses advised against:	Only the ident	tified 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					



Page 2 of 18

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

	Product identification:	BIO-DIFF 1 RTU REAGENT
	Identification number:	-
	Authorisation number:	-
	Hazard pictograms:	GHS02 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	
	Endocrine Disrupting Pro	perties:
	No known endocrine disrup	oting properties assessment: According to the results of its assessment, this substance is not



Page 3 of 18

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

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.			



Page 4 of 18

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

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	CTION 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 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 responders:				
	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 enter drains. Risk of explosion.				
6.3.	Methods and materials for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Cover drains. Collect, bind and pump off spills.			



Page 5 of 18

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

6.3.2.	For cleaning:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.			
6.3.3.	Other information:	Do not use tools that may cause sparks.			
6.4.	Reference to other se	ections			
	See Section 7 for information on safe handling.				
	See Section 8 for information on personal protective equipment.				
	See Section 13 for dis	sposal information.			

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



Page 6 of 18

Irade name: BIO-DIFF 1 RTU REAGENT										
Produ	ct code:	BD1-RT	U	Date of	f compilat	tion:	03.04.20	023.	Version:	6
Further information on storage co				condition	ns:	and chen	ot place the un do not use emp nicals. Do not so Section 10).	ty conta	iners for stori	ng other
7.3.	Specific er	nd use(s)								
	Recomme	ndations:			-					
	Industrial	sector spe	cific solutio	ns:	-					
SECTIO	ON 8. Expos	ure contr	ols/persona	al protec	tion					
8.1.	Control pa	rameters								
							exposure limit term values			
Substance		CAS I	No		I		В	Biological limit values		
Methai	Methanol 67-56		5-1	200		mg/m ³	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*),		ne*),	
	* For all results pertaining creatinine levels, creatinine concentration < 0.5 g/l and > 3.0 g/l may not be taken into consideration									
Substa	nce: -									
EC No:	-		CAS No:	-						
DNEL				i						
					Indust	rial				
Route	of	A	Acute		Acute		Chroni	ic	Ch	ronic
exposi	ıre:	effe	ect local	effect systemic		С	effect lo	cal	effect	systemic
Oral		-		-			-		-	
Inhalat	ion	260 m (metha	•		260 mg/m³ (methanol)		260 mg/m ³ (methanol)		260 mg/m ³	(methanol)
Derma		-		40 mg/	'kg (metha	nol)			40 mg/kg (methanol)
Critical	physical par	ameters:	solubility, fla	mmabili	ty, corrosiv	vity:		-		
					Consur	ner	T			
Route of			Acute		Acute		Chroni			ronic
exposure: effect loca		ect local		ect systemi		effect lo	cal		systemic	
Oral -		. 2		g (methan	ol)	-		8 mg/kg (n	nethanol)	
Inhalation 50 mg/m ³ (methanol)			50 mg/ (metha			50 mg/m ³ (methanol)		50 mg/m ³ (methanol)		
Derma	I	-			g (methan	ol)			8 mg/kg (n	
PNFC										



Page 7 of 18

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

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



Page 8 of 18

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

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

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



Page 9 of 18

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

	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		

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

SECTION 11. 1	SECTION 11. Toxicological information									
11.1. Inforn	nformation on hazard classes as defined in Regulation (EC) No 1272/2008									
Acute	Acute toxicity:									
Route of exposure:	Method	nod Species LD ₅₀ /LC		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

BIO-DIFF 1 RTU REAGENT

Page 10 of 18

Trade name:		<u> </u>	IO-DIFF I KIL) REAGEINT	······································
Product code:	BD1-RTU	Date of con	npilation:	03.04.2023.	Version: 6
Inhalation:	No informatio available	n rat	LC ₅₀	o 4 h	3.88 mg/l (methanol)
Specific	target organ toxici	ty - single exposur	e (STOT-SE):		
. •		ific effects		arget organ	Note
Oral:	No information a			nation available	-
Dermal:	No information a	vailable	No inforn	nation available	-
Inhalation:	alation: No information available				mixture causes damage to organs
Aspiration	on hazard:	No ir	formation availa	able	
Irritation	n and corrosion				
	Exposure	time Spec	ies Evaluat	ion Method	Note
Skin corrosion/irritatio	on -	-	-	-	drying-out effect resulting in rough and chapped skin
Serious eye damage/irritatior	- 1	-	-	-	irritations of mucous membranes
Sensitiza	ation				
Skin sensitization	: Does not car	use sensitization.			
Respiratory sensitization:	No informat	ion available			
Sympto	ms related to the pl	nysical, chemical a	nd toxicological	characteristics:	
Oral exposure:		vel irritation, acido Absorption may ca	•	•	g unwell, vomiting, strong kidney, cardiac.
Dermal exposure:		firritation, defattin yed systemic effec	J .	posure may cause	e absorption and greater
Inhalation exposure:	•	and possible lung ache. Absorption	_	•	or concentration, dizzines
Eye exposure:		lindness, irreversib			s, lesser possibility of /isual impairments may
Reneate	d dose toxicity (sub	pacute subchronic	chronic)		
repeate	a dose toxicity (sur	Jacate, Japenionie	,		



Page 11 of 18

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

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 ta	rget organ	toxicity -	repeated	exposure	(STOT-RE):
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	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	-



Page 12 of 18

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

	CMR effects (carcinogenicity, mutagenicity, re	productive toxicity)
	Carcinogenicity:	No information available
	Mutagenicity in-vitro:	No information available
	Genotoxicity:	No information available
	Mutagenicity in-vivo:	No information available
	Germ cell mutagenicity:	No information available
	Reproductive toxicity:	No information available
	Summary of evaluation of the CMR properties:	No information available
11.2.	Information on other hazards:	
11.2.1.	Endocrine disrupting properties:	
	No known endocrine disrupting properties that affect human health.	
11.2.2.	Other information:	
	-	

SECTION 12. Ecological information									
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	-			



Page 13 of 18

Trade name:		BIO-DIFF 1 RTU REAGENT									
Product code	e:	BD1-RTU		Date of	compilation:	03	3.04.202	.3.	Vers	ion:	6
Crustacea:		EC ₅₀	48 hou	rc	No information		No No information available available		mation - able		
Algae/aquatic plants:		IC ₅₀	72 hou	rc	information ilable	No inforr availa	nation ble	No inform availa	mation - able		
Other organis	ms	-									
12.2. Persis	stence	and degrada	ability								
Abiot	ic deg	gradation									
	С	egradation h	alf-lives)	Method			Eva	luation		Note
Marine water					information ava	ilable	No in	format	ion ava	ilable	-
resh water No information available				No	information ava	ailable No informat			ion ava	ilable	-
Air	No i	nformation a	vailable	No	information ava	ilable	lable No informat			mation available -	
Soil	No information available				information ava	nilable No information			ion ava	ilable	-
Biode	egrada	ation									
Biodegradation % Degradation Time (days)					Method	E	valuatio	n		No	te
-		-		-		No in availa	formatic ble	on	-		
		lative potenti			(a)						
Value		eter partition centration	pH	°C	Method		Fyalua	ntion		N	ote
_	No availal	information	- -	-	-			Evaluation information lable		11	ote
Bioco	ncent	ration Factor	(BCF)			:			1		
Value	0 0 0 0 0 0 0 0 0 0 0 0 0 0	Spec			Method	E	Evaluatio	n		No	ote
No informatio	n	No informati available			No information available		No information available		No information available		tion



Page 14 of 18

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

	Chr	onic ecotoxicity	/						:		1
	Value Dose		Dose	Exposure time		Species	Me	thod	Evalu	ation	Note
Chroni	ronic toxicity on fish LC ₅₀		LC ₅₀	No information available	in			nation ole	No inforn available	nation	-
	Chronic toxicity on EC ₅₀		EC ₅₀	No information available		o formation vailable	No inform availat		No inforn available	nation	-
12.4.	Mol	bility in soil									
		wn or predicte	d distribut	ion in enviro	nmen	tal compartn	nents:				
	No	information av	ailable								
	Surf	ace tension:									
	Value			°C	Concentration			Method			Note
	No avai	No information No available availab		nformation	No ir	No information available		No information available		-	
	۸۵۰	ovation / doco									
	Aas	orption / deso A/D coef									
Transp	ort	Henry's co		log Kow		Evaporation rate		Method		Note	
Soil-W	ater	-	formation	No inform available	ation			No information available		-	
Water-	Air	No in available	formation	No inform available	ation			No information available		-	
Soil-Aiı	r	No in available	formation	No inform available	ation	No informa available	ation	No information available		-	
12.5.		ults of PBT and									
12.6		stance(s) in the			eet the	e criteria for	PRI or vi	VR			
12.6.	End	ocrine disrupti							ndocrine dis		



Page 15 of 18

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

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	
	•	posed of according to the national and local rules and regulations. Do not e. Submit for disposal to the legal person authorized by the Ministry of protection.
13.1.2.	Wasta sadas (wasta darigna	tions according to Laws
13.1.2.	Waste codes/waste designa No information available	tions according to Law.
	NO IIIIOIIIIatioii avaliable	
13.1.3.	Waste codes/waste designa	tions according to Low:
	15 01 10*: packaging that co substances	ontains residual hazardous substances or is contaminated with hazardous
13.1.4.	Sewage disposal – relevant i	nformation:
	Waste must not be disposed	d of into the sewage system.
13.1.5.	Other disposal recommenda	ations:
	authorized by the ministry in	act's remains into the sewage system. Submit the remains to the collectors of charge. Do not dispose of the packaging into the sewage system. Submit ors authorized by the ministry in charge. Do not dispose of in places where
13.1.6.	Relevant Community provisi	ons:
	Disposal must be made acco	ording to official regulations.
SECTION	N 14. Transport information	
	Transporting/shipment by roa	d (ADR)
UN num	ber:	1230
	per shipping name:	Methanol
Transpo	rt hazard class(es):	3 (6.1)
Packing	-	II
	mental hazards:	-
Special p	precautions for user:	-



Page 16 of 18

Trade name:	BIO-DIFF 1 RTU REAGENT				
Product code:	BD1-RTU	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: -	

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



Page 17 of 18

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

	Authorisations and/or rest	rictions 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	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			



Page 18 of 18

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

16.3.		literature references source of data:	-
16.4.	Classification and procedure us 1272/2008 (CLP)		used to derive the classification for mixture according to Regulation (EC)
Classific	cation	1	Classification procedure
_			-
16.5.	S. Relevant H statements (num		ber and full text)
		225	Highly flammable liquid and vapor.
	H:	301+311+331	Toxic if swallowed, in contact with skin or if inhaled.
		370	Causes damage to organs (eyes).
16.6.	Trai	ning advice:	-
			** "X" in the product code marks different volumes (different packaging of the product)
16.7.	16.7. Further information:		We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEY. Functions according to addition to Observed and affect according to
ANNEX: Exposure scenario resulting to Chemical safety assessment



SAFETY DATA SHEET

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

Page 1 of 16

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

1.1.	Product identifier	Product identifier				
	Trading name:	BIO-DIFF	2 RTU REAGE	NT		
	Chemical name:	-				
	Catalogue number:	BD2-RTU	2-RTU			
1.2.	Relevant identified us	es of the su	s of the substance or mixture and uses advised against			
	Uses:		Buffered ı	Buffered red component of Bio-Diff RTU kit.		
	Uses advised against:		Only the i	dentified uses are advised.		
	Reason why uses advi	vised against: device, registered at the		uct is intended for use only as an <i>in vitro</i> diagnostic medical gistered at the Agency for Medicinal Products and Medical nd there is no reason to use it for other purposes		
1.3.	.3. Details of the supplier of the safety data sheet					
	Supplier:	Supplier: Bid				
	Address: M		Medjugorska	Лedjugorska 59, Zagreb		
	Telephone number:		+385 1 24099	+385 1 2409997		
	Fax no.:		+385 1 2404039 msds@biognost.hr			
	e-mail of competent	person:				
	National contact:		-			
1.4.	Emergency telephone	number				
	National Protection a	nd Rescue D	Directorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	ECTION 2. Hazards identification				
2.1.	Classification of the substance or mixture				
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)				
	Hazard class and category 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	Section 16		
2.2.	Label elements				
	Product identification:	BIO-DIFF 2 R	RTU REAGENT		
	Identification number:	-			
	Authorization no.:	-			
	Hazard pictograms:	-			



Other hazards

Endocrine Disrupting Properties:

No known endocrine disrupting properties.

2.3.

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

Page 2 of 16

Trading name:		BIO-DIFF 2 RTU REAGENT				
Product code: BI		BD2-RTU	Date of compilation: 14 November 2022	Version: 4		
	Signal wo	rd:	-			
	Hazard statements:		-			
	Precautionary statements:		-			
	Suppleme (EU):	tal hazard information	-			

CAS/ Classification acco	
EC/ Index no. REACH Weight % content (or range) Registration No (or range) Identification name Regulation (EG) 1272/2008 (G)	C) No

substances

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



Page 3 of 16

Trading name:		BIO-DIFF 2 RTU REAGEN	IT
Product code:	BD2-RTU	Date of compilation: 14 Noveml	per 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		
	-		

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:	Sand or clay barriers.				



Page 4 of 16

Trading name:		BIO-DIFF 2 RTU REAGENT	
Product code:	BD2-RTU	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 sections			
	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 generation:		Secure proper ventilation.	
	Measures to protect the environment:	Measures to protect the environment:		
	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: ver		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.	
			ufacturer's original packaging.	
	ERACITICAMENTS FOR STORAGE FOOMS AND VESSALS.		Keep away from food and drink. Keep the containers ightly closed.	
	Advices for storage equipment: be dir		The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.	
	Further information on storage conditions: and che		ot place the unused material in the storage room do not use empty containers for storing other sicals. Do not store with incompatible materials (see on 9).	
7.3.	Specific end use(s)			



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

amended by Regulation (EU) No. 2020/878

Page 5 of 16

Trading name:				BIO-D	IFF 2 I	RTU REAGEI	NT	
Product code:	BD2-RT	·U	Date o	of compila	ation:	14 Novem	ber 2022	Version: 4
D	1							
Recommer				-				
Industrial s	ector spe	cific solutio	ns:	-				
SECTION 8. Exposu	ıre contr	ols/persona	al protec	tion				
8.1. Control pa	rameters							
				Occupati	ional ex	posure limit		
Substance		CAS I	No	values/	short to	erm values	Biolo	gical limit values
				ppm		mg/m³		
_		-		-		-	No informa	ition available
Substance name:								
EC No: -		CAS No:	_					
DNEL		C/15 110.						
				Industr	rial			
		Acute		Acute		Chron	ic	Chronic
Route of exposure:				ct systemi	С	effect local		effect systemic
Oral	-		-			-		
Inhalation	-		-			-	-	
Dermal	-		-			-	-	
Critical physical para	ameters:	solubility, fla	ammabilit	y, corrosiv	ity:	-		
				Consun	ner			
Route of exposure:	/	Acute Ac		Acute			ic	Chronic
Noute of exposure.	effe	ect local effect		ct systemi	emic effect local		ocal	effect systemic
Oral	-		-			-	-	
Inhalation	-		-			-		
Dermal			-			-	-	
PNEC								
Environmental prote	ection tar	get		PN				
Fresh water				No information available				
Freshwater sediments				No information available				
Marine water				No information available				
Marine sediments				No information available				
Food chain					No information available			
Microorganisms in s	sewage tr	eatment				ation availabl		
Soil (agricultural)				No	No information available			



Page 6 of 16

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

Air			No information available					
8.2.	Exposure controls							
8.2.1.		Appropriate engineering controls						
0.2.1.	Substance/mixture relate measures to prevent expeduring identified uses:	d	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.					
	Structural measures to preexposure:	event	No information available					
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.					
	Technical measures to pr exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.					
8.2.2.	Personal protection equi	Personal protection equipment						
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) o visor.						
8.2.2.2.	Skin protection							
0.2.2.2.			rotective gloves must be according to the EU Directive 2016/425/EEC and andard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min					
	TITLE CAIL DECTION.		Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (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 inf	formation available					
8.2.3.	Environmental exposure	controls						
	Substance/mixture relate measures to prevent exp		See Section 6					
	Structural measures to preexposure:	revent	Use modern equipment.					
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.					
	Technical measures to prexposure:	event	See Section 6					

SECTION 9. Physical and chemical properties



Page 7 of 16

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

	Value	Method	
Physical state:	liquid	No information available	
Color:	red	No information available	
Odour/odour threshold:	no odor/no information available	No information available	
Melting point / freezing point:	No information available	No information available	
Boiling point or initial boiling point and boiling range:	No information available	No information available	
Flammability:	No information available	No information available	
Lower and upper explosion limit:	No information available	No information available	
Flash point:	No information available	No information available	
Auto-ignition temperature:	No information available	No information available	
Decomposition temperature:	No information available	No information available	
pH:	5.5 – 6.5	No information available	
Kinematic viscosity:	No information available	No information available	
Solubility:	No information available	No information available	
Partition coefficient n-octanol/water (log value):	No information available	No information available	
Vapour pressure:	No information available	No information available	
Density and/or relative density	No information available	No information available	
Relative vapour density:	No information available	No information available	
Particle characteristics:	No information available	No information available	

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



BD2-RTU

Trading name:

Product code:

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

amended by Regulation (EU) No. 2020/878

Page 8 of 16

BIO-DIFF 2 RTU REAGENT

Date of compilation: 14 November 2022 Version: 4

Acute toxi	city:					
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 ta	rget organ toxicity – si	ngle exposure (STOT SE):			
	3 3	c effects		organ		Note
Oral exposure:	No information a	available	No informati		-	
Dermal exposure:	No information a	available	No informati	No information available -		
Inhalation exposure	: No information a	available	ailable 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	on					
Dermal exposure:	No information availa	able				
Inhalation exposure:	No information availa	able				
Symptoms	related to the physica	l, chemical and	toxicological chara	cteristics		
Oral exposure:	Swallowing may consensation; higher I In case of vomiting concentration may	levels of conceng, aspiration cau	tration may cause uses coughing, diff	nausea, abdo	ominal pa	ain and vomiting
	concentration may cause suffocation. Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.					



Page 9 of 16

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

Inhalation exposure: Eye exposure:		Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.								
		Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.								
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	No avail	information able	No information available	No informati available	on	No information available	No informatio available	on -		
Subacute dermal	No avail	information able	No information available	No informati available	on	No information available	No informatio available	n -		
Subacute inhalation	No information available		No information available	No informati available	on	No information available	No informatic available	n -		
Subchronic oral	No information available		No information available	No informati available	on	No No information infor available available		on -		
Subchronic dermal	No avail	information able	No information available	No informati available	on	No information available	No informatio available	n -		
Subchronic inhalation	No information available		No information available	No informati available	on	No information available	No informatic available	on -		
Chronic oral	No avail	information able	No information available	No informati available	on	No information available	No informatic available	on -		
Chronic dermal	No avail	information able	No information available	No informati available	on	No information available	No informatio available	n -		
Chronic inhalation	No information available		No information available	No informati available	on	No information available	No informatic available	on -		
C: £ -	+0***	organ tanksis			TOT 10					
Specific	target	1	y – repeated e pecific effects	xposure (S	IUIK		an	Note		
Subacute oral			tion available		Target organ No information available -		- Note			
Subacute dermal			tion available			nformation avai		-		
Subacute inhalat			tion available			nformation avai		_		



Page 10 of 16

Trading name:		BIO-DIFF 2 RTU REAGENT					
Product code:	BD2-RTU	Date of compilation:	14 November 2022	Version: 4			
110ddct codc.	DDZ KIO	Date of complication.	14 NOVEITIBET ZOZZ	VCISION: 4			

Subchr	onic oral	No informat	ion available	No information available	-			
Subchro	onic dermal	No informat	ion available	No information available	-			
Subchr	onic inhalation	No informat	ion available	No information available	-			
Chronic	oral	No informat	ion available	No information available	-			
Chronic	dermal	No informat	ion available	No information available	-			
Chronic	Chronic inhalation No information		ion available	No information available	-			
	i							
	CMR effects (c	arcinogenicity	; mutagenicity; rep	roductive toxicity)				
	Carcinogenicity:		Current studies	Current studies on test animals did not indicate carcinogenic effects.				
	Mutagenicity in-vitro:		Current in vit	Current in vitro tests did not indicate mutagenic effects.				
	Genotoxicity:		No information	No information available				
	Mutagenicity i	n-vivo:	Current in viv	Current in vivo tests did not indicate mutagenic effects.				
	Germ cell mut	agenicity:	No information available					
	Reproductive toxicity:		No toxicity on reproductive organs was determined in reproductive organs.					
	Summary of ev	valuation of th	e CMR properties:	-				
	.i							
11.2.	Information or	n other hazard	s:					
11.2.1.	Endocrine disr	upting proper	ties:					
	No known end	locrine disrupt	ing properties that	affect human health.				
11.2.2.	Other informa	tion:						

Information on other hazards:
Endocrine disrupting properties:
No known endocrine disrupting properties that affect human health.
Other information:
-

SECTION 12. Ecologi	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) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note	



Soil

No information available

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

Page 11 of 16

Trading name:		BIO-DIFF 2 R	TU REAGENT	
Product code:	BD2-RTU	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. Pe	rsistence and degradability	stence and degradability						
Ab	Abiotic degradation							
	Degradation half-lives	Method	Evaluation	Note				
Marine water	No information available	No information available	No information available	-				
Fresh water	No information available	No information available	No information available	-				
Air	No information available	No information available	No information available	-				

No information available

No information available

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

Oc	tanol-water partition	coefficien	t (log Ko	ow)		
Value	Concentration	рН	°C	Method	Evaluation	Note
_	No information available	-	-	No information available	No information available	-
Bic	oconcentration factor	(BCF)				
Value	e Spec	ies		Method	Evaluation	Note



Page 12 of 16

	me:	BIO-DIFF 2 RTU REAGENT								
Product co	de:	BD2-RTU Date			mpilation:	14 No	vember 2	022	Vers	ion: 4
No informat available		No inform available		nation No information available		No information available			No information available	
Chi	ronic eco	otoxicity								
V	alue	Dose		osure ime	Species	Met	hod	Evalu	ation	Note
Chronic toxi	icity on fi	ish LC ₅₀	No infori availa	mation i	No nformation available	No inform availab	ation i	No nforma ivailable		_
Chronic toxi crustacea (<i>L</i>	•	EC ₅₀	No No		nformation			No nforma available		
Kno		redicted distribut	on in e	environmer	ntal compart	ments:				
		tion available								
	rface tens	sion:				Mothe		<u> </u>		
Sur No info	face tens	sion: °C No	No	oncentration information ilable		Metho formational		-	N	ote
No info ava	Value ormation ailable	sion: °C No information available / desorption	No	informatio	on No inf	ormatio		-	N	ote
No info	value ormation ailable sorption A/	or Sion: Or No information available	No ava	informatio	on No inf	ormation ole			N	ote
No info ava	value ormation ailable sorption A/	No information available / desorption D coefficient hry's constant information	No ava	information ilable og Kow	on No inf availab Evaporati	ormation ole on rate	n	hod	N ₁	
Sur No info ava Ad: Transport	value ormation hilable sorption A/ Her	occion: Occion No information available / desorption D coefficient ory's constant information ole information	No ava	information ilable og Kow nformation able	Evaporati No inform	ormation on rate	Met	hod mation	N ₁	



Page 13 of 16

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

12.6.	Endocrine disrupting properties				
	No known endocrine disrupting prop	erties that affect the environment.			
12.7.	Other adverse effects				
	No adverse effects are expected.				
SECTIO	N 13. Disposal considerations				
13.1.	Waste treatment methods				
13.1.1.	Product/Packaging disposal:				
	Submit for disposal to the legal per Protection.	son authorized by the Ministry of Environmental and Nature			
13.1.2.	Waste codes/waste designations ac	cording to Law:			
	No information available				
13.1.3.	Waste treatment – relevant informa	tion:			
	No information available				
13.1.4.	Sewage disposal – relevant informa				
	Waste must not be disposed of into	o the sewage system.			
13.1.5.	Other disposal recommendations:				
	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):				



Page 14 of 16

Trading name:		BIO-DIFF 2 KTO KEAGENT	
Product code:	BD2-RTU	Date of compilation: 14 November 2022	Version: 4
Packing group:		-	
Environmentally haz	ardous:	-	
Special precautions	for user:	-	
Transportin	ıg/shipment by r	ail (RID)	
UN number:		Not subject to transport regulations.	
UN proper shipping	name:	-	
Transport hazard cla	iss(es):	-	
Packing group:		-	
Environmentally haz	ardous:	-	
Special precautions	for user:	-	
Inland wate	erway transport (ADN)	
UN number:		Not subject to transport regulations.	
UN proper shipping	name:	-	
Transport hazard cla	ass(es):	-	
Packing group:		-	
Environmentally haz	ardous:	-	
Special precautions	for user:	-	
Transportin	g/shipment by s	sea (IMDG)	
UN number:		Not subject to transport regulations.	
UN proper shipping	name:	-	
Transport hazard cla	ass(es):	-	
Packing group:		-	
Environmentally haz	ardous:	-	
Special precautions	for user:	-	
Transportin	g/shipment by a	air (ICAO-TI/IATA-DGR)	
UN number:		Not subject to transport regulations.	
UN proper shipping	name:	-	
Transport hazard cla	ss(es):	-	
Packing group:		-	
Environmentally haz	ardous:	-	
Special precautions	for user	-	



Page 15 of 16

Trading name:		BIO-DIFF 2 RTU REAGENT	
Product code:	BD2-RTU	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:	-		



SAFETY DATA SHEET

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

Page 16 of 16

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

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



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

amended by Regulation (EU) No. 2020/878

Page 1 of 16

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

SECTIO	ON 1: Identification of t	the substan	ce/mixture a	and of the company/undertaking		
1.1.	Product identifier	identifier				
	Trading name:	BIO-DIFF	BIO-DIFF 3 RTU REAGENT			
	Chemical name:	-	-			
	Catalogue number:	BD3-RTU	BD3-RTU			
1.2.	Relevant identified use	es of the sub	of the substance or mixture and uses advised against			
	Uses:		Buffered b	lue component of Bio-Diff RTU kit.		
	Uses advised against:		Only the identified uses are advised.			
	Reason why uses advis	sed against:	device, reg	roduct is intended for use only as an <i>in vitro</i> diagnostic medical e, registered at the Agency for Medicinal Products and Medical es and there is no reason to use it for other purposes		
1.3.	Details of the supplier	of the safet	y data sheet			
	Supplier:	l	BioGnost Ltd.			
	Telephone number:		Medjugorska 59, Zagreb			
			+385 1 2409997			
			+385 1 2404039			
	e-mail of competent p	erson: <u> </u>	msds@biogn	ds@biognost.hr		
	National contact:		-			
1.4.	Emergency telephone number					
	National Protection and Rescue Direction Medical information: Other information:		irectorate:	112		
			+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 subst	tance.	-			
2.1.2.	Additional information					
	-					
*For fu	*For full text of Hazard- and EU Hazard-statements: see Section 16					
2.2.	Label elements					
	Product identification:	BIO-DIFF 3 R	TU REAGENT			
	Identification number:	-				
	Authorization no.:	-				
	Hazard pictograms:	-				



Endocrine Disrupting Properties:

No known endocrine disrupting properties.

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

Page 2 of 16

Trading name:	BIO-DIFF 3 RTU REAGENT						
Product code: BD3-RTU		Date of compilation:	14 November 2022	Version:	6		
Signal v	vord: statements:	-					
	ionary statements:	-					
Supplei (EU):	metal 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	-

SECTI	CTION 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	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.						



Page 3 of 16

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

	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.				
4.3.	Indication of any immediate medical attention and special treatment needed					
	-					

SECTIO	SECTION 5. Firefighting measures						
5.1.	Extinguishing media						
	Suitable extinguishing media: Small fire - water spray, dry powder, CO 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 personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.				
	Emergency procedures:	Mark the area using proper signs.				
6.1.2.	For emergency responders:					
	Wear protective equipment (see Section 8).					
6.2.	Environmental precautions:					
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.					
6.3.	Methods and material for containment and cleaning up					
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.				



Page 4 of 16

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

6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.				
6.3.3.	Other information:	-				
6.4.	Reference to other sections					
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.					

	ON 7. Handling and storage							
7.1.	Precautions for safe handling							
7.1.1.	Protection measures							
	Measures to prevent fire:		Keep away from sources of heat and ignition. Do not smoke.					
	Measures to prevent aerosol and dust generati	ion:	Secure proper ventilation.					
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.					
	Other measures:		-					
7.1.2.	Advice on general occupational hygiene:							
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.							
7.2.	Conditions for safe storage, including any incompatibilities							
	Technical measures and storage conditions:	ven	p in tightly closed and upright set containers in a well tilated storage rooms, and away from sources of heat, light, and other incompatible substances.					
	Packaging materials:	Maı	nufacturer's original packaging.					
	Requirements for storage rooms and vessels:		ep away from food and drink. Keep the containers ntly closed.					
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.						
	Further information on storage conditions:	and che	not place the unused material in the storage room I do not use empty containers for storing other micals. Do not store with incompatible materials (see tion 9).					



Soil (agricultural)

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

Page 5 of 16

Trading name:				ВІ	O-DIFF 3	RTU REAGE	NT	
Product code:	BD3-RT	·U	Date	of cor	mpilation:	14 Novem	nber 2022	Version: 6
Recomme	ndations:				_			
		cific solution	nc.		-			
maasman	sector spe	cinc solution	113.					
SECTION 8. Expos	ure contr	ols/persona	al protec	tion				
8.1. Control pa		0.0, personi	protec					
				Occi	upational e	exposure limit		
Substance		CAS I	No		•	term values	Biolog	gical limit values
					ppm	mg/m³		
-		-			-	-	No informa	tion available
Substance - name:								
EC No: -		CAS No:	-					
DNEL		1	·					
				Inc	dustrial			
Acute		Acute		Chronic		Chronic		
Route of exposure:	effe	ect local effec		ect sys	vstemic effect lo		ocal	effect systemi
Oral	-		-			-	-	
Inhalation	-		-			-		
Dermal	-		-			-	-	
Critical physical par	ameters:	solubility, fla	ımmabili	ty, cor	rosivity:	-		
				Co	nsumer			
Route of exposure:	/	Acute		Acut	e	Chron	nic	Chronic
Route of exposure.	effe	ect local	effe	ect sys	temic	effect lo	ocal	effect systemi
Oral	-		-			-		
Inhalation	-		-			-	-	
Dermal	-		-			-	-	
PNEC								
Environmental protection target				PNEC				
Fresh water				No information available				
Freshwater sediments					No inforr	nation availab	le	
Marine water				No information available				
Marine sediments					No inforr	nation availab	le	
Food chain					No inforr	nation availab	le	
Microorganisms in sewage treatment				No inforr	nation availab	le		

No information available



Page 6 of 16

Trading name:	BIO-DIFF 3 RTU REAGENT							
Product code:	BD3-RTU	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 related measures to prevent expo		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.				
	Structural measures to pr exposure:	event	No information available				
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.				
	Technical measures to pre exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.				
8.2.2.	Personal protection equip	ment					
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.					
8.2.2.2.	Skin protection						
			ective gloves must be according to the EU Directive 2016/425/EEC and dard EN 374.				
	Hand protection:		Glove material: nitrile rubber				
			Glove thickness: ≥0.50 mm Break through time: >480 min				
	()ther skin protection:		r antistatic clothing made of natural fibers (such as cotton) with long ves (EN 13034), and shoes that cover the entire foot (EN 10335).				
8.2.2.3.	Respiratory protection:	Protect filter fo	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 ') used when concentration levels exceed GVI.				
8.2.2.4.	Thermal hazards:	No inf	formation available				
8.2.3.	Environmental exposure	controls					
	Substance/mixture related measures to prevent expo		See Section 6				
	Structural measures to prevent exposure:		Use modern equipment.				
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.				
	Technical measures to proexposure:	event	See Section 6				

SECTION 9. Physical and chemical properties



Page 7 of 16

Trading name:	BIO-DIFF 3 RTU REAGENT				
Product code:	BD3-RTU	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 No information available	
Lower and upper explosion limit:	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



Page 8 of 16

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

11.1. Informatio	n on hazard classes as	defined in Regu	lation (EC) No 12	72/2008					
Acute toxic		<u> </u>		,					
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure	osure time Resu				
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 – si	<u> </u>							
		ic effects		t organ		Note			
Oral exposure:	No information		No informati		-				
Dermal exposure:	No information		No information available -		-				
Inhalation exposure	:: No information	available	No informati	on available	-				
Aspiration	hazard:	No infor	mation available						
Irritation a	nd corrosion:								
IIIItation a	Exposure time	Species	Evaluation	Method		Note			
Skin irritation:	-	rabbit	-			11010			
Eye irritation:	_	rabbit	-		•				
	:	:	÷	:					
Sensitization	on								
Dermal exposure:	No information avail	able							
Inhalation exposure:	No information available								
Symptoms	related to the physica	al, chemical and t	oxicological char	acteristics					
Oral exposure:	sensation; higher In case of vomitin	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.							



Page 9 of 16

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

coughing. Eve exposure: Direct eye			alation of large amounts of vapors in inadequately ventilated perimeter may cause ighing, sneezing, headache and nausea.					
		Direct eye co	Direct eye 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	No avail	information able	No information available	No informati available	on	No information available	No informatio available	on -
Subacute dermal	No avail	information able	No information available	No informati available	on	No information available	No informatio available	n -
Subacute inhalation	No avail	information able	No information available	No informati available	on	No information available	No informatic available	n -
Subchronic oral	No avail	information able	No information available	No informati available	on	No information available	No informatic available	on -
Subchronic dermal	No avail	information able	No information available	No informati available	on	No information available	No informatio available	n -
Subchronic inhalation	No avail	information able	No information available	No informati available	on	No information available	No informatic available	on -
Chronic oral	No avail	information able	No information available	No informati available	on	No information available	No informatic available	on -
Chronic dermal	No avail	information able	No information available	No informati available	on	No information available	No informatio available	n -
Chronic inhalation	No avail	information able	No information available	No informati available	on	No information available	No informatic available	on -
C: £ -	+0***	organ tanksis			TOT 10			
Specific	target	1	y – repeated e pecific effects	xposure (S	IUIK		an	Note
Subacute oral			tion available		Target organ No information available		- Note	
Subacute dermal			tion available			nformation avai		-
Subacute inhalat			tion available			nformation avai		_



Page 10 of 16

Trading name:	BIO-DIFF 3 RTU REAGENT							
Product code:	BD3-RTU	Date of com	Date of compilation: 14 November 2022		Version: 6			
Subchronic oral	No informa	tion available	No ir	nformation available	_			

	chronic oral No informatio		tion available	No information available	-			
Subchronic dermal No informatio		No informat	tion available	No information available	-			
Subchrc	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	roductive toxicity)				
	Carcinogenicit	y:	Current studies	Current studies on test animals did not indicate carcinogenic effects.				
	Mutagenicity i	n-vitro:	Current <i>in vitro</i> tests did not indicate mutagenic effects. No information available					
	Genotoxicity:							
	Mutagenicity i	n-vivo:	Current in viv	Current <i>in vivo</i> tests did not indicate mutagenic effects. No information available				
	Germ cell muta	agenicity:	No information					
	Reproductive t	oxicity:	No toxicity on reproductive organs was determined in reproductive organs.					
· · · · · · · · · · · · · · · · · · ·	Summary of ev	aluation of th	e CMR properties:	-				
11.2.	Information or	other hazard	c.					
11.2.1.								
	No known endocrine disrupting properties that affect human health.							
11.2.2.	Other information	•	g properties that	aa.				

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 time	Species	Method	Evaluation	Note		



Page 11 of 16

Trading name:	BIO-DIFF 3 RTU REAGENT							
Product code:	BD3-RTU	Date of compilation:	14 November 2022	Version: 6				
Troduct code.	DD3 KTO	Date of complication.	14 NOVEITIBET ZUZZ	VCISION: 0				

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. F	Persistence and degradability	istence and degradability							
/	Abiotic degradation								
	Degradation half-lives	Method	Evaluation	Note					
Marine water	No information available	No information available	No information available	-					
Fresh wat	ter 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	No information available	No information available	No information available	No information available				

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



Page 12 of 16

Trading name: BIO-DIFF 3 RTU REAGENT													
Product o	code:	BD3-	-RTU	Г	ate of co	mpil	mpilation: 14 November 2022		2022		Version:	6	
No inform available			No informavailable		ion No informatio available			No information available		n			
C	Chronic ec	otoxici	ity										
	Value		Dose		osure ime	Spe	ecies	Met	hod	Eva	aluatic	on	Note
Chronic to	oxicity on	fish	LC ₅₀	No infor avail	mation	No inforr availa	mation able	No informa availab	ation	No inforr availa		۱ -	
Chronic to crustacea	-		EC ₅₀	No infor avail	mation	No inforr availa	mation able	No informa availab	ation	No inforn availa		า -	
12.4. N	Mobility ir	n soil											
		•	ed distributi	on in e	environme	ntal c	ompart	ments:					
	No inform		vailable										
S	Surface te Value	nsion:	°C		oncentrati			Matha	۵.			Note	
ir	No nformatio available			No	information		No infavailat	ormatior	Method nation -			Note	
Δ	Adsorptio	n / des	orption										
Transport	•		efficient constant	lc	og Kow	E۱	Evaporation rate		Method			No	ote
No information available		nformation	No ir availa	nformation able		o inform ailable	ation	No information available		-			
Soil-water	avanc	Water-air No information available		No information available		ı No	No information available		No information available		_		
	No		nformation			av	ailable		availabl	е			



Page 13 of 16

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

12.6.	Endocrine disrupting properties					
	No known endocrine disrupting p	roperties that affect the environment.				
12.7.	Other adverse effects					
	No adverse effects are expected.					
SECTION	N 13. Disposal considerations					
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
	Submit for disposal to the legal Protection.	person authorized by the Ministry of Environmental and Nature				
	:					
13.1.2.	Waste codes/waste designation	s according to Law:				
	No information available					
13.1.3.	Waste treatment – relevant information:					
	No information available					
13.1.4.	Sewage disposal – relevant info	rmation:				
	Waste must not be disposed of	into the sewage system.				
13.1.5.	Other disposal recommendation	ns:				
	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:					
SECTION	N 14. Transport information					
	Transporting/shipment by road (A	ADR)				
UN num	ber:	Not subject to transport regulations.				
UN prop	per shipping name:	-				
Transpoi	rt hazard class(es):	-				



Trading name:

SAFETY DATA SHEET

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

BIO-DIFF 3 RTU REAGENT

Page 14 of 16

Product code:	BD3-RTU	Date of compilation:	14 November 2022	Version: 6
Packing group:		-		
Environmentally ha		-		
Special precautions		-		
	ng/shipment by rai			
UN number:		Not subject to transport	regulations.	
UN proper shipping		-		
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:	-		
Further information	n: The produc	t is not subject to classification	n.	



Page 15 of 16

Trading name:	BIO-DIFF 3 RTU REAGENT					
Product code:	BD3-RTU	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 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:	_				



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

Page 16 of 16

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

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classifi	cation	Classification procedure		
-		-		
16.5.	Relevant H statements (num	ber and full text)		
	H: -	-		
16.6.	Training advice:	-		
16.7		** "X" in the product code marks different volumes (different packagings of the product)		
16.7.	Further information:	We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

ANNEX: Exposure scenario resulting to Chemical safety assessment



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

Page 1 of 16

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

SECTI	ON 1: Identification of	the substance	e/mixture	e and of the company/undertaking
1.1	Product identifier			
	Trading name:	BUFFER SO	LUTION, p	oH 6.8
	Chemical name:	-		
	Catalogue number:	PUF68-OT-	X**	
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against
	Uses:		Buffer so	olution for use in hematology, 6 mM.
	Uses advised against:		Only the	e identified uses are advised.
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.	
1.3	Details of the supplier of the safety data sheet			
	Supplier:		BioGnost Ltd.	
	Address:		Medjugorska 59, Zagreb	
	Telephone number:		+385 1 2409997	
	Telefax.:		+385 1 2404039	
	e-mail of competent person:		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	ON 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	ON, pH 6.8	
	Identification number: -			
	Authorization number: -			
	Hazard pictograms:	-		



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

Page 2 of 16

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

	Signal word:	-	
	Hazard statements:	-	
	Precautionary statements:	-	
	Supplemetal hazard information (EU):	-	
2.3	Other hazards		
	Endocrine Disrupting Prope	erties:	
	No known endocrine disrupti	ng properties	
	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.	-

SECTI	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.		



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

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

Page 3 of 16

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 case of inadequate ventilation use adequate airways protective equipment (see Section 8).				
6.2	Environmental precautions:				
	Do not dispose of in sewage, or Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National rate (NPRD) on 112.			
6.3	Methods and material for con-	tainment and cleaning up			
6.3.1.	Bunding, covering of drains; capping procedures: Sand or clay barriers.				
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents.			
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).			
6.4	Reference to other sections				



Page 4 of 16

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

See Section 7 for information about secure handling.

See Section 8 for information about personal protective equipment.

See Section 13 for information about containment.

SECTIO	ON 7. Handling and storage						
7.1	Precautions for safe handling						
7.1.1.	Protection measures						
	Measures to prevent fire:		Use in well ventilated storage rooms.				
	Measures to prevent aerosol and dust generation	n:	Secure proper ventilation.				
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.				
	Other measures:		-				
7.1.2.	Advice on general occupational hygiene:						
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.						
7.2	Conditions for safe storage, including any incompatibilities						
	Technical measures and storage conditions:		ghtly closed and upright set containers in a ated storage roomsat temperatures ranging 25 °C.				
	Packaging materials:	Manufactu	urer's original packaging.				
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.					
	Advices for storage equipment:	must be re	ge must be made of hard material; floors esistant to chemicals. There must be no drain sly leads into sewage system. Secure proper n.				
	Further information on storage conditions:	Do not place the unused material in the storage ro and do not use empty containers for storing other chemicals. Do not store with incompatible material (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										
Substance		CAS No	Occupational values/short	exposure limit term values	Biological limit values						
			ppm	mg/m³							



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

Page 5 of 16

Trading name	2:						BUFFER SOLUTION, pH 6.8							
Product code:	Product code: PUF68-OT-X**			Date	of c	of compilation: 2		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			Chro			Chronic			
exposure:		effect	local	effec	t system	nic		effect l	ocal		effect systemic			
Oral	- -			-			-			-				
Inhalation	-			-			-			-				
Dermal				-			-			-				
Critical physica	l parar	meters: s	solubility,	flamma										
		T		1		onsi	umer							
Route of		Acute			Acute		Chronic			Chronic				
exposure:		effec	t local		t system	nic					effect systemic			
Oral		-		-			-			-				
Inhalation		-		-			-			-				
Dermal		-		-			-			-				
PNEC						Τ								
Environmental	protec	ction tar	get				NEC							
Fresh water						No information available								
Freshwater sed	iment	S				No information available No information available								
Marine water						+								
Marine sedime	nts					+	o inform							
Food chain						-	o inform							
Microorganism		ewage tr	eatment			-	o inform							
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				•				poms. Use persona			
pro	event	exposur	e during	identifie	ed uses:	protective equipment. Do not eat, drink or smoke in the workspace.								



Page 6 of 16

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. Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.				
	Technical measures to prevent ex	(posure:					
8.2.2.	Personal protection equipment						
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lowe levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.					
8.2.2.2.	Skin protection						
	Hand protection:	Protec	ective nitrile gloves, 0.11 mm thick (EN 374).				
	Other skin protection:		ar antistatic clothing made of natural fibers (such as cotton) 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	modern equipment.				
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the lace.				
	Technical measures to prevent exposure:	See Se	ection 6				

SECTI	SECTION 9. Physical and chemical properties								
9.1	Information on basic physical and chemical properties								
		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						



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

Page 7 of 16

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	_				



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

								Pa	ge 8 of 1	6
Trading name:										
Product code:	Р	UF68-OT-X**		Date of comp	compilation:		ec 2022	Version:		4
	8			1						
			ific effects			et 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: No information available		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/irritatio	n	-		-	-		-	-		
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 ormation informa ailable 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:

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

Page 9 of 16

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

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

No information available



Page 10 of 16

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

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

12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC 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



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

Page 11 of 16

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

Abioti	c degr	adation									
	D	egradation h	alf-liv	es	N	Method		Evaluatio	n		Note
Marine water	vater 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	Evaluation		on		Note
No information No information available available		No information available		No information available		-					
Chron	ic eco	toxicity					i			•	
			se	•	osure ime	Species	N	/lethod	Evalu	uation	Note
value Dose tii		mation	No information	No info	ormation	No inform	nation	-			



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

Page 12 of 16

		!						Page 12 of 1	Ь
Trading	name:		В	UFFER SO	LUTION	, pH 6.	.8		
Product code: PUF68-OT-X**			Date of compilation: 22			22 De	c 2022	Version:	4
Chronic toxicity on crustacea (<i>Daphnia</i>)		No information available			mation informat able 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	ion _			
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 i		rmation				
Water-ai	No	information	No informatio	available No information available		No information available		_	
Soil-air	No availa	information able	No information available No information available		No information available		-		
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							



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

Page 13 of 16

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

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:			
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collector 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	orecautions for user:	-			
	Transporting/shipment by ra	ail (RID)			
UN num	ber:	Not subject to transport regulations			
UN prop	er shipping name:	-			
Transpo	rt hazard class(es):	-			
Packing	group:	-			
Environr	nentally hazardous:	-			
Special p	orecautions for user:	-			
	Inland waterway transport (A	ADN)			



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

Page 14 of 16

Trading name:		BUFFER SOLUTION	I, pH 6.8		
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	ECTION 15. Regulatory information				
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorization and/or restrictions of use				
	Authorizations: -				
	Restrictions: -				



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

Page 15 of 16

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

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



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

Page 16 of 16

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

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classifi	cation	Classification procedure		
-		-		
16.5.	Relevant H statements (num	ber and full text)		
	H: -	-		
16.6.	Training advice:	-		
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

Page 1 of 16

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				
	Trading name:	BUFFER SO	LUTION, p	H 7.2	
	Chemical name:	-			
	Catalogue number:	PUF72-OT-	X**		
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against	
	Uses:		Buffer so	olution for use in hematology, 6 mM.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplier of the safety data sheet				
	Supplier:	Supplier:		BioGnost Ltd.	
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent person:		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	ON 2. Hazards identification			
2.1	Classification of the substance or mixture			
2.1.1	Classification according to R	Classification according to Regulation (EC) No 1272/2008 (CLP)		
	Hazard class and cate	egory code:	Hazard statements*:	
	Not identified as hazardous	substance.	-	
2.1.2.	Additional information			
	-			
*For fu	ll text of Hazard- and EU Haza	rd-statements: see	SECTION 16	
2.2	Label elements			
	Product identification:	BUFFER SOLUT	ION, pH 7.2	
	Identification number: -			
	Authorization number: -			
	Hazard pictograms:	-		



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

Page 2 of 16

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

	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	Endocrine Disrupting Prope	erties:
	No known endocrine disrupti	ng properties
	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.	-		

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.			



Page 3 of 16

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

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

SECTION 5. Firefighting measures				
5.1	Extinguishing media			
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO_2 Large fire - water spray or alcohol-resistant foam		
	Unsuitable extinguishing media:	No information available		
5.2	Special hazards arising from the substance or mixture			
	Hazardous combustion products:	No information available.		
5.3	Advice for firefighters			
	Use a self-contained open-circuit	compressed air breathing apparatus and fireproof clothing.		
5.4	Additional information			
	Do not contaminate the environm	ent with extinguishing media.		

SECTIO	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					



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

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

Page 4 of 16

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

See Section 7 for information about secure handling.

See Section 8 for information about personal protective equipment.

See Section 13 for information about containment.

SECTIO	ON 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:		Use in well ventilated storage rooms.		
	Measures to prevent aerosol and dust generation	n:	Secure proper ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:		-		
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.				
7.2	Conditions for safe storage, including any incom	patibilities			
	Technical measures and storage conditions:	well ventil	Keep in tightly closed and upright set containers in a well ventilated storage roomsat temperatures ranging from 15 to 25 °C.		
	Packaging materials:	Manufactu	Manufacturer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away	y from food and drink. Keep the containers sed.		
	Advices for storage equipment:	must be re	ge must be made of hard material; floors esistant to chemicals. There must be no drain sly leads into sewage system. Secure proper n.		
	Further information on storage conditions:	conditions: Do not place the unused material in tand do not use empty containers for chemicals. Do not store with incomparts (see Section 10).			
7.3	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	_			

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



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

Page 5 of 16

Trading name:	BUFFER SOLUTION, pH 7.2											
Product code:	PUF72-OT-X** Date			e of	compila	ition:	22 [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	effec	t syste	mic	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	o inforn	nation a	availabl	e		
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	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.					



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

Page 6 of 16

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

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



SAFETY DATA SHEET ling to Regulation (FC) No. 1907/2

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

Page 7 of 16

Trading name:		BUFFER SOLUTION	l, 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	ON 10. Stability and reactivity	
10.1	Reactivity:	No information available
10.2	Chemical stability:	No information available
10.3	Possibility of hazardous reactions:	No information available
10.4	Conditions to avoid:	No information available
10.5	Incompatible materials:	No information available
10.6	Hazardous decomposition products:	No information available

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	_



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

				, ,				Page 8 of	16
Trading name:				BUFFER SO	LUTION,	pH 7.2			
Product code:	Р	UF72-OT-X**		ate of compila	ation:	22 Dec 2	2022	Version:	4
	,		:		:			:	1
		Spec	ific effects		Target o	organ		Note	
Oral:	١	lo information	available	No in	formation a	available	-		
Dermal:	١	lo information	available	No in	formation a	available	-		
Inhalation:	١	lo information	available	No in	formation a	available	-		
Aspirat	ion ha	zard:		No information	available.				
Irritatio	n and	corrosion							
		Exposur	e time	Species	Evaluati	on M	lethod	Note	
Skin		-		-	-	_		-	
corrosion/irritat	ion:								
Serious eye damage/irritation	on	-		-	-	-		-	
- aumage, mitatio									
Sensitiz	zation								
Skin sensitizatio	n:	-							
Respiratory sens	sitizatio	on: -							
Sympto	oms re	lated to the pl	nysical, chemi	cal and toxicolo	gical chara	acteristics			
Oral exposure:		No informati	on available						
Dermal exposur	e:	No informati	on available						
Inhalation expo	sure:	No informati	on available						
Eye exposure:		No informati	on available						
Repeat	ed dos	se toxicity (sub	acute, subch	ronic, chronic)					
		Dose	Exposure time	Species	Method	d	Evaluatior	n Note	
Subacute oral	No avai	information ilable	No information available	No information available	No informa availab	ation	No informatio available	on -	
Subacute dermal	No avai	information ilable	No information available	No information available	No informa availab	ation	No informatio available	on -	

No

information

available

No information

available

Subacute

inhalation

No

information

available

No

information

available

No

information

available



Reproductive toxicity:

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

Page 9 of 16

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

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 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 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 in	formatio	n available	-	
Subacute derma		No informa	ation available		No in	formatio	n available	-	
Subacute inhalat	ion	No informa	ation available		No in	formatio	n available	-	
Subchronic oral		No informa	ation available		No in	formatio	n available	-	
Subchronic dern	nal	No informa	ation available		No in	formatio	n available	-	
Subchronic inha	lation		ation available		No in	formatio	n available	-	
Chronic oral			ation available		-		n available	-	
Chronic dermal			ation available				n 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	en muta	agenicity:		No inform	iation av	/allable			

No information available



Page 10 of 16

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

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

12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC 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



PUF72-OT-X**

Trading name:

Product code:

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

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

BUFFER SOLUTION, pH 7.2

Date of compilation: 22 Dec 2022 Version: 4

	c degi	radation								
	D	egradatio	n half-li	ves	l	Method	Evaluatio	n		Note
Marine water	No	information	on availa	able	No in	formation ble	No informatio available	n	-	
Fresh water	No	information	on availa	able	No in	formation ble	No informatio available	n	-	
Air	No	information	on availa	able	No in	formation ble	No informatio	n	-	
Soil	No	information	on availa	able	No in	formation ble	No informatio available	n	-	
Biode	oradat	tion								
% Degradati			ne (days))	ı	Method	Evaluatio	n		Note
No information		No	inform		No in	formation	No informatio			rmation
available		available			availa	DIE	available		availabl	e
		ative pote		: -: + <i>(</i>	l = = 1/ =	.)				
	ol-wat	ative pote ter partition centration		Н	log Kow °C	v) Method	Evalu	ation	-	Note
Octan Value	ol-wat	ter partitio	on coeffi p	Н	°C	Method		ation	-	Note
Octan Value 	ol-wat	ter partitio	p coeffi	Н	°C	Method		ation	-	Note
Octan Value 	ol-wat	ter partition centration	p coeffi	Н	°C -	Method			-	Note
Octan Value Biocor Value No information	Conc	ter partition centration	p p -	H	°C	Method Method ormation	-	on	-	
Value	Conc	ter partition centration ration fact Sp No	p p p p p p p p p p p p p p p p p p p	H	°C	Method Method ormation	Evaluat No informat	on		
Octan Value Biocor Value No information	Conc	ter partition centration ration fact Sp No	p p p p p p p p p p p p p p p p p p p	H	°C	Method Method ormation	Evaluat No informat	on		
Octan Value Biocor Value No information available	ncentr	ter partition centration ration fact Sp No	p p p p p p p p p p p p p p p p p p p	H	°C	Method Method ormation	Evaluat No informat	on		
Value Biocor Value No information available	ol-water Conco	ration fact Sp No available	p p p p p p p p p p p p p p p p p p p	ation	°C	Method Method ormation	Evaluat No informat	on		



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

Page 12 of 16

								Page 12 of 1	6
Trading	name:		BU	IFFER SOL	JTION,	pH 7.	2		
Product code: PUF72-OT-X**		Date o	Date of compilation: 2		22 Dec 2022		Version:	4	
	toxicity on ea (<i>Daphnia</i>) EC ₅₀	information i	No nformation available	No inform availat		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	No information available	No inform available	nation	No ir availa	nformation able	-	
12.5.	Results of	PBT and vPvB asses	ssment						
	Based on	available data, the p	product does not	contain any	PBT or v	vPvB su	bstances.		
12.6.	Endocrine	disrupting propert	ies						
	No known	endocrine disrupti	ng properties tha	t affect the	environr	ment.			
12.7.	Other adv	erse effects							
	No advers	e effects are expect	ted.						
		osal consideration	S						
13.1	Waste tr	reatment methods							



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

Page 13 of 16

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

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



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

Page 14 of 16

Trading name:	BUFFER SOLUTION, pH 7.2						
Product code:	PUF72-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: -	

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: -					



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

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

Page 15 of 16

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

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

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



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

Page 16 of 16

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

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
Classifi	cation	Classification procedure			
-		-			
16.5.	Relevant H statements (num	ber and full text)			
	H: -	-			
16.6.	Training advice:	-			
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	
-	