

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

The kit contains:

Bio-Diff 1 RTU reagent

Bio-Diff 2 RTU reagent

Bio-Diff 3 RTU reagent

Buffer tablet, pH 6.8

Buffer tablet, pH 7.2



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

	ON 1: Identification of the subst	ance/mixture a	nd of the company/undertaking	
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:	device, registe	s intended for use only as an <i>in vitro</i> diagnostic medical ered at the Agency for Medicinal Products and Medical nere is no reason to use it for other purposes.	
1.3.	Details of the supplier of the safety data sheet			
	Supplier:	BioGnost Ltd.		
	Address:	Medjugorska	59, Zagreb	
	Telephone number:	+385 1 24099	97	
	Telefax:	+385 1 2404039		
	e-mail of competent person:	msds@biognost.hr		
	National contact:			
1.4.	Emergency telephone numbers			
	National Protection and Rescue	e Directorate:	112	
	Medical information:		+385 1 2348 342	
	Other information:		-	

SECTIO	ON 2. Hazards identification					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification according to Regulation (EC) No	1272/2008 (CLP)				
	Hazard class and category code:	Hazard statement*:				
	Flam. Liq. 2	H225				
	Acute Tox. 3	H301				
	Acute Tox. 3	H311				
	Acute Tox. 3	H331				
	STOT SE 1	H370				
2.1.2.	Additional information					
	-					
* For fu	ull text of Hazard- and EU Hazard-statements: see	e SECTION 16				
2.2.	Label elements					



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	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 Prop			
	No known endocrine disrupting properties			
	·	<b>issessment</b> : According to the results of its assessment, this substance is not a		



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SECTION 3. Composition/information on ingredients							
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)			
67-56-1/ 200-659-6/ 603-001-00-X	01-2119433307- 44-xxxx	99 %	methanol	Flam. Liq. 2, H225 Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 STOT SE 1, H370			

4.1.	Description of first aid measures				
	General notes:	First aider needs to protect himself.			
	Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration, if necessary also oxygen. In case of irregular breathing or respiratory arrest provide artificial respiration.			
	Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.			
	Following ingestion:	Rinse with water and expectorate. Make the afflicted person drink one glass (100 ml) of 40% ethanol (adult dose). Call a doctor immediately (mention methanol ingestion). Only in exceptional cases, if no medical care is available within one hour, induce vomiting (only in fully conscious persons) and make victim drink ethanol again (approx. 0.3 ml of a 40% alcoholic beverage/kg body weight/hour). Do not attempt to neutralise.			
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.			
4.2.	Most important symptoms and effects, both acute and delayed				
	Following inhalation:	Irritation to the airways and possible damage to the lung probably only through very high vapor concentrations, then even absorptive-toxic effects.			
	Following skin contact:	Minor/no irritation, degreasing action, following massive contact watch for danger of skin absorption and possibly delayed onset of systemic effects.			
	Following eye contact:	Slight through to moderate irritation due to the liquid and concentrated vapors, conjunctivitis, later chemosis, apparently minor probability of cornea damage, later occurring visual disturbances are caused not primarily through local contact but are systemically related (following absorption).			
	Following ingestion:	Stomach and bowel irritation, feeling unwell, nausea, vomiting, strong abdominal pain. Absorption may cause toxic effects.			



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

SECTI	ECTION 5. Firefighting measures					
5.1.	Extinguishing media					
	Suitable extinguishing media:	water spray, foam, dry powder, CO <sub>2</sub>				
	Unsuitable extinguishing media:	No information available				
5.2.	Special hazards arising from the sul	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	Additional information				
	Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.					

SECTIO	TION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency 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.			



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

SECTIO	ON 7. Handling and storage		
7.1.	Precautions for safe handling		
7.1.1.	Protection measures		
	Measures for fire prevention:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition and direct sunlight. Do not smoke. Take precautionary measures against static discharge.	
	Measures for preventing spray and dust formation:	Secure proper ventilation. Prevent formation of aerosols.	
	Environmental precautions:	Prevent spilling into the sewage system and waterways.	
	Other measures:	Protect against electrostatic charges.	
7.1.2.	Advice on general occupational hygiene:		
	Do not eat, drink or smoke in the workspace. Thore	oughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompa	tibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.	
	Packaging materials:	Manufacturer's original packaging.	
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.	
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.	



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Further inf	condition	ns:	and cher	not place the ur do not use emp nicals. Do not s Section 10).	oty conta	iners for stori	ng other		
7.3. Specific er	nd use(s)								
Recomme	Recommendations: -								
Industrial	sector spe	cific solutio	ns:	-					
SECTION 8. Expos		ols/person	al protec	tion					
8.1. Control pa	rameters	I		ı			ı		
		646	N.I.			exposure limit term values			
Substance		CAS No		ppm		mg/m <sup>3</sup>	] B	iological limit	values
Methanol	anol 67-56		6-1	200		260	24.7 mmol/mol of cr (7.0 mg/g of creatini		ne*),
* For all results pert	taining cre	l eatinine leve	els, creati	l nine conce	entrati	on < 0.5 g/l and		-shift urinary /I may not be	
Substance: -									
EC No: -		CAS No:	-						
DNEL			·						
				Indust	rial				
Route of		Acute		Acute		Chron			ronic
exposure:	effe	ect local	effe	ect system	ic	effect lo	ocal	effect	systemic
Oral	260	/ 3	200			-		<u> </u>	
Inhalation	260 m (metha	•	260 mg/m <sup>3</sup> (methanol)			260 mg/m <sup>3</sup> (methanol)		260 mg/m³ (methanol)	
Dermal	-			40 mg/kg (methanol)				40 mg/kg (	(methanol)
Critical physical par	ameters: :	solubility, fl					-		· ,
				Consu		i i			
Route of		Acute		Acute	-		ic	Ch	ronic
exposure:	effe	ect local	effect systemic				ocal	effect	systemic
Oral	-		8 mg/kg (me		nol)	-		8 mg/kg (n	nethanol)
Inhalation	50 mg (metha			50 mg/m³ (methanol)		50 mg/m <sup>3</sup> (methanol)		50 mg/m <sup>3</sup> (methanol)	ı
Dermal	-		8 mg/k	g (methar	nol)			8 mg/kg (n	nethanol)
DNEC									



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Environmental protection target			PNEC	
Fresh wat	er		154 mg/l (methanol)	
Freshwate	er sediments		570.4 mg/kg (methanol)	
Marine water			15.4 mg/l (methanol)	
Marine se	diments		No information available	
Food chai	in		No information available	
Microorga	anisms in sewage treatment		100 mg/l (methanol)	
Soil (agric	cultural)		23.5 mg/kg (methanol)	
Air			No information available	
8.2.	Exposure controls			
8.2.1.	Appropriate engineering measures			
	Substance/mixture related measures to prevent exposure during identified uses:	prot	the product in well ventilated rooms. Use personal ective equipment. Do not eat, drink or smoke in the kspace.	
	Structural measures to prevent exposure:	No i	nformation available	
	Organisational measures to prevent exposure:		anization of work in order to reduce other worker's ence during work process.	
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.		
8.2.2.	Personal protection equipment			
8.2.2.1.	Eye and face protection:	prot	e shield and safety glasses. Use equipment for eye ection tested and approved under appropriate government dards such as EN 166(EU).	
8.2.2.2.	Skin protection:			
		The protective gloves to be used must comply with the specification of EC Directive 2016/425 and the related stan EN374.  Full contact:  Glove material: butyl rubber		
	Hand protection: Splas		Glove thickness: 0.70 mm  Break through time: > 480 min  ash contact:  Gloves material: viton (R)  Glove thickness: 0.70 mm  Break through time: > 120 min	



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

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



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

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

SECTIO	ON 11. To	cicological information					
11.1.	Informat	ion on hazard classes as	defined in Regu	ation (EC) No 1272	/2008		
Route of exposure:		Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results	
Oral:		No information available	rat	LD <sub>50</sub>	-	125.13 mg/kg (methanol)	
Derma	ıl:	No information available	rabbit	LD <sub>50</sub>	-	375.13 mg/kg (methanol)	



Trade name:

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Inhalation:	No information available	rat	LCs	io 4	3.88 (meth	_
Specific	target organ toxicity	cinale evacu	ro (STOT SE):			
Specific		ic effects		Target organ	Not	to
Oral:	No information av			mation availab		
Dermal:	No information ava			mation availab		
Inhalation:	No information ava		Eyes		mixture caus damage to o	
Aspiration	on hazard:	No i	nformation avail	able		
Irritation	and corrosion					
	Exposure ti	me Spe	cies Evalua	tion Metho	od Note	<del>)</del>
Skin corrosion/irritation -			-	-	drying-out effer resulting in rou chapped skin	
Serious eye damage/irritatior	- 1	-	-	-	irritations of m membranes	ucous
Sensitiza	ation					
Skin sensitization	: Does not caus	se sensitization.				
Respiratory sensitization:	No information	n available				
Sympton	ms related to the phy	vsical chamical	and toyicologica	Lobaractoristic	c.	
Oral exposure:	Stomach and bowe	el irritation, acid	osis, drop in blo	od pressure, fe	eeling unwell, vomitin liver, kidney, cardiac.	g, strong
Dermal exposure:	Minimum level of i possibility of delay			xposure may c	ause absorption and	greater
Inhalation exposure:	Airways irritation a drowsiness, heada		-		f vapor concentration	, dizzines
Eye exposure:		ndness, irreversi			mosis, lesser possibili ve. Visual impairmen	•
Repeate	d dose toxicity (suba	cute, subchroni	c, chronic)			
epeate	a access tomerty (sub-	25.00, 25.0001110111	-, 3 56,			



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

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



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

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



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Crustacea:		EC <sub>50</sub>	48 hours		No information		No information available		ation le	1 -	
Algae/aquatic plants:		IC <sub>50</sub>	72 hours		nformation able	No infor availa	mation able	No informa availabl		-	
Other organis	ms	-	-	-		-		-		_	
12.2. Persi	stence a	and degrada	ability								
		adation									
	1	egradation h	nalf-lives		Method			Evalu	ation		Note
Marine water	No in	formation a	ıvailable	No i	nformation ava	ilable	No ir	nformatio	n ava	ilable	-
Fresh water	sh water No information available				nformation ava	ilable	No ir	nformatio	n ava	ilable	-
Air	No in	formation a	ıvailable	No information available No ir			nformatio	n ava	ilable	-	
Soil	No in	formation a	ıvailable	No i	nformation ava	n available No info			nformation available -		-
Biode	egradat	ion									
% Degradati		Time (da	2VC)		Method		Evaluatio	n .		Note	
- 70 Degradati	-				- Incured		nformati	on		14010	•
						availa	able				
12.3. Bioad	ccumula	ative potent	ial								
Octa	nol-wat	er partition	coefficient	(log Ko	ow)						
Value	Conc	entration	рН	°C	Method		Evalu	ation		No	te
-	No i availab	nformation le	-	-	-		o inform ⁄ailable	nation	-		
			(DCE)								
Value	oncentr	ation Factor Spec			Method		Evaluati	on		Note	<u> </u>
No informatio	n l	· · · · · · · · · · · · · · · · · · ·		No ii					No ir		
available		No information available					No information available		No information available		



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	Chr	onic ecotoxicit	ty								
	Va	llue	Dose	Exposure time		Species	Me	thod	Evalu	ation	Note
Chronic toxicity on fish LC		LC <sub>50</sub>	No information available		o formation ⁄ailable	No inform availal	available		nation	-	
Chronic toxicity on crustacea (Daphnia)		EC <sub>50</sub>	No information available		o formation ⁄ailable	No inform availal	mation No information available		nation	-	
12.4.	Mo	bility in soil									
	Kno	wn or predicte	ed distribut	ion in enviro	nment	tal compartn	nents:				
	No	information av	vailable								
	Surf	face tension:									
		Value		°C		Concentrati	on		Metho	d	Not
	No informavailable		No information available		No information available		No information available		vailable	-	
	Ads	orption / desc				***					
Transp	ort	A/D coef Henry's c		log Kov	W	Evaporatio	n rate	Me	ethod	١	Note
Soil-W	ater	No ir available	nformation	No inform available	ation	No information available		No information available		-	
Water-	Air	No ir available	nformation	No inform available	ation	No informa available	ation	No information available		-	
Soil-Air No available		No ir available	nformation	No inform available	ation	No informa	ation	No info availabl	rmation e	-	
	_										
12.5.	Res	ults of PBT and	d vPvB asse	ssment							
	Sub	stance(s) in th	e mixture d	o(es) not me	et the	criteria for	PBT or vl	PvB			
12.6.	Fnd	ocrine disrupt	ing propert	ies							



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12.7.	Other adverse effects			
	No adverse effects are expecte	d.		
SECTION	N 13. Disposal considerations			
13.1.	Waste treatment methods			
13.1.1.	Product/Packaging disposal:			
		osed of according to the national and local rules and regulations. Do not a submit for disposal to the legal person authorized by the Ministry of rotection.		
1212	Wasta sadas (wasta dasignat	ions assording to Law		
13.1.2.	Waste codes/waste designat  No information available	ions according to Law.		
	INO IIIIOIIIIAUOII AVAIIADIE			
13.1.3.	Waste codes/waste designat	ions according to Low:		
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances			
	i			
13.1.4.	Sewage disposal – relevant information:			
	Waste must not be disposed of into the sewage system.			
13.1.5.	Other disposal recommendations:			
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.			
13.1.6.	Relevant Community provisions:			
	Disposal must be made acco	rding to official regulations.		
SECTION	N 14. Transport information			
	Transporting/shipment by road	d (ADR)		
UN num	ber:	1230		
UN prop	er shipping name:	Methanol		
Transpo	rt hazard class(es):	3 (6.1)		
Packing		ll		
Environr	nental hazards:	-		
Special p	precautions for user:	-		



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

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

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



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

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

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



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Trade name:		BIO-DIFF 1 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 used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classific	catior	1	Classification procedure
-			-
16.5.	5.5. Relevant H statements (num		ber and full text)
		225	Highly flammable liquid and vapor.
	H:	301+311+331	Toxic if swallowed, in contact with skin or if inhaled.
		370	Causes damage to organs (eyes).
16.6.	Trai	ning advice:	
			** "X" in the product code marks different volumes (different packaging of the product)
16.7.	16.7. Further information:		We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment	
-	



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

1.1.	Product identifier				
	Trading name:	BIO-DIFF 2	BIO-DIFF 2 RTU REAGENT		
	Chemical name:	-	-		
	Catalogue number:	BD2-RTU	BD2-RTU		
1.2.	Relevant identified use	es of the subs	stance or mi	xture and uses advised against	
	Uses:		Buffered i	red component of Bio-Diff RTU kit.	
	Uses advised against:		Only the i	dentified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes		
1.3.	Details of the supplier	of the safety	data sheet		
	Supplier: Bi		ioGnost Ltd.		
	Address:	N	Medjugorska 59, Zagreb		
	Telephone number:	Telephone number: +		385 1 2409997	
	Fax no.:	Fax no.: +		+385 1 2404039	
	e-mail of competent p	e-mail of competent person: <u>m</u>		msds@biognost.hr	
	National contact:	-			
1.4.	Emergency telephone number				
	National Protection and Rescue Dire		ectorate:	112	
	Mational Frotection at	ia rieseae Bii			
	Medical information:			+385 1 2348 342	

SECTIO	SECTION 2. Hazards identification							
2.1.	Classification of the substance or mixture							
2.1.1.	Classification according to Regula	Classification according to Regulation (EC) No 1272/2008 (CLP)						
	Hazard class and category code: Hazard statements*:							
	Not identified as hazardous subst	ance.	-					
2.1.2.	Additional information							
	-							
*For fu	ll text of Hazard- and EU Hazard-sta	atements: see S	Section 16					
2.2.	Label elements							
	Product identification:	BIO-DIFF 2 R	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

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Trading name	2:	BIO-DIFF 2 RTU REAGENT								
Product code	: BD2-RTU	Date of compilation:	14 November 2022	Version: 4						
Signal	word:	-								
Hazar	d statements:	-								
Precautionary statements:		-								
Suppl (EU):	emetal hazard information	-								
2.3. Other	hazards									

	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
Index no.			Contains no hazardous	12/2/2000 (CLF)

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



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

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

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

SECTIO	SECTION 6. Accidental release measures						
6.1.	Personal precautions, protective equipment and emergency procedures						
6.1.1.	For non-emergency 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 con	tainment and cleaning up					
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.					



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Trading name:	BIO-DIFF 2 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 generat	ion:	Secure proper ventilation.				
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.				
	Other measures:		-				
7.1.2.	2. Advice on general occupational hygiene:						
	Do not eat, drink or smoke in the workspace. T	ghly wash hands after work and before eating.					
7.2.	Conditions for safe storage, including any incompatibilities						
	Technical measures and storage conditions:	venti	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.				
	Packaging materials:	Manı	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:	be re	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 o	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).				
7.3.	Specific end use(s)						



Soil (agricultural)

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

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									rage 5 or 10		
Trading name:	g name: BI						IO-DIFF 2 RTU REAGENT				
Product code:	BD2-RTU Date of compilation: 14 November 2022 Version:						Version: 4				
Recommer	dations										
		· · · · · · · · · · · · · · · · · · ·			-						
Industrial s	ector spe	cific solutio	ns:		-						
SECTION 8. Exposu	ire contr	ols/nersona	al protect	tion							
8.1. Control pa		013, per30110	protect								
<u> </u>				Occi	upational e	exposi	ıre limit				
Substance		CAS I	No	va	lues/short	term	values	Biolo	ogical limit values		
					ppm	m	g/m³				
-		-			-		-	No inform	ation available		
Substance name:											
EC No: -		CAS No:	-								
DNEL			i								
				Inc	dustrial						
		Acute Acu		Acut	e Chronic		ic	Chronic			
Route of exposure:	effect local		effect systemic		temic	effect local		ocal	effect systemic		
Oral	-		-			-			-		
Inhalation	-		-			-			-		
Dermal	-		-			-			-		
Critical physical par	ameters:	solubility, fla	mmability	y, cor	rosivity:		-				
				Co	nsumer						
Doubs of our course	,	Acute		Acut	e	Chron		ic	Chronic		
Route of exposure:	effe	ect local	effe	ct sys	temic	effect lo		ocal	effect systemic		
Oral	-		-			-			-		
Inhalation	-		-			-			-		
Dermal	-		-			-			-		
PNEC											
Environmental protection target					PNEC						
Fresh water					No infor	mation	n availabl	e			
Freshwater sediments					No infor	mation	n availabl	e			
Marine water					No information available						
Marine sediments					No information available						
Food chain					No information available						
Microorganisms in sowage treatment					No information available						

No information available



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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.	Evaccura controls						
	Exposure controls  Appropriate engineering controls						
8.2.1.			5				
	Substance/mixture relate measures to prevent exp during identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.				
	Structural measures to p exposure:	revent	No information available				
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.				
	Technical measures to prexposure:	revent	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:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.					
8.2.2.2.	Skin protection						
			otective 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				
	I ITHER SVIN PROTECTION:		ar antistatic clothing made of natural fibers (such as cotton) with long eves (EN 13034), and shoes that cover the entire foot (EN 10335).				
8.2.2.3.	Respiratory protection:	filter f	octive 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 pexposure:	revent	Use modern equipment.				
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.				
	Technical measures to prexposure:	event	See Section 6				

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



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Trading 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**



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

11.1. Informatio	n on hazard classes as	defined in Regu	ılation (EC) No 12	72/2008			
Acute toxic							
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure	time	Results	
Oral exposure:	No information available	_	LD <sub>50</sub>	_		_	
Dermal exposure:	No information available	-	LD <sub>50</sub>	-		-	
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-		-	
Specific ta	rget organ toxicity – sir	ngle exposure (S	STOT SE):				
	Specific	c effects	Targe	t organ		Note	
Oral exposure:	No information a	ıvailable	No informati	on available	-		
Dermal exposure:	No information a	ıvailable	No informati	No information available -			
Inhalation exposure	: No information a	ıvailable	No informati	on available	-		
Aspiration  Irritation a	hazard: nd corrosion:	No infor	mation available				
	Exposure time	Species	Evaluation	Method		Note	
Skin irritation:	-	rabbit	-				
Eye irritation:	-	rabbit	-				
Sensitizatio	on						
Dermal exposure:	No information availa	able					
Inhalation exposure: No information available							
Symptoms	related to the physical	, chemical and t	toxicological chara	acteristics			
Oral exposure:	sensation; higher lo	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of					
		concentration may cause suffocation.  Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.					



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

Inhalation exposure:		Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.						
Eye exposure: Direct eye co sensation.			ntact may cau	se slight to	mod	erate irritation,	lacrimation a	and burning
Reneate	nd dose	e toxicity (sub	acute, subchro	onic chroni	(c)			
Керсис		Dose Dose	Exposure time	Species	<u>C)</u>	Method	Evaluation	Note
Subacute oral	No availa	information able	No information available	No informati available	on	No information available	No informatio available	on -
Subacute dermal	No availa	information able	No information available	No informati available	on	No information available	No informatio available	n -
ubacute No information nhalation available		No information available	No informati available	on	No information available	No informatic available	n -	
Subchronic oral	ubchronic oral No information available		No information available	No informati available	on	No information available	No informatio available	n -
Subchronic dermal	No availa	information able	No information available	No informati available	on	No information available	No informatio available	n -
Subchronic inhalation	No availa	information able	No information available	No informati available	on	No information available	No informatic available	on -
Chronic oral	No availa	information able	No information available	No informati available	on	No information available	No informatic available	on -
Chronic dermal	No availa	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		WD 06:175 / CT	TOT 10			
Specific	target	1	y – repeated e pecific effects	xposure (S	IOIK		an	Note
Subacute oral			tion available		Target organ  No information available -		- Note	
Subacute dermal			tion available			nformation avai		-
Subacute inhalat			tion available			nformation avai		_



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

			-	i e e e e e e e e e e e e e e e e e e e			
Subchro	onic oral	No information	ı available	No information available	-		
Subchro	onic dermal	No information	ı available	No information available			
Subchro	onic inhalation	No information	ı available	No information available			
Chronic	oral	No information	available	No information available	-		
Chronic	dermal	No information	ı available	No information available	-		
Chronic inhalation No information		available	No information available	-			
	CMR effects (c	arcinogenicity; m	utagenicity; repro	oductive toxicity)			
	Carcinogenicity:		Current studies on test animals did not indicate carcinogenic effects.				
	Mutagenicity in-vitro:		Current in vitro tests did not indicate mutagenic effects.				
	Genotoxicity:		No information available				
	Mutagenicity i	n-vivo:	Current in vivo tests did not indicate mutagenic effects.				
	Germ cell muta	agenicity:	No information available				
	Reproductive t	oxicity:	No toxicity on organs.	reproductive organs was deter	mined in reproductiv		
	Summary of ev	/aluation of the C	MR properties:	-			
				ustra de la constanta de la co			
11.2.	Information or	other hazards:					
11.2.1.	Endocrine disr	upting properties	•				
	No known end	locrine disrupting	properties that a	affect human health.			
11.2.2.	Other information	tions:					

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

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



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Trading name:		BIO-D	IFF 2 RTU R	EAGENT		
Product code:	BD2-RTU	Date of compile	ation: 14 N	lovember 2022	Version: 4	
			:			
				No		

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

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

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

	paccumulative potenti					
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	-
Bic	oconcentration factor	(BCF)				
Value	Spec	ies		Method	Evaluation	Note



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Trading n	ame:	BIO-DIFF 2 RTU REAGENT									
Product c	ode:	BD2-RTU		Date of compilation:		14 November 2022		Ver	Version: 4		
No information No inform available available		nation No information available		on	No information available			No information available			
Cł	ronic ec	otoxicity									
\	/alue	Dose		osure ime	Spe	ecies	Met	hod	Eva	luation	Note
Chronic to	kicity on	fish LC <sub>50</sub>	No infor availa	mation	No infori availa	mation able	No informa availab	ation	No inforn availa		-
Chronic to: crustacea (	-	EC <sub>50</sub>	No infor availa	mation	No infori availa	mation able	No informa availab	ation	No inforn availa		-
Kr N	o inform	predicted distributi ation available	ion in e	environme	ntal o	compart	ments:				
Sı	ırface ter					I					
	Value	°C	Concentration		Method		<u> </u>	Note			
	o formatio railable	No n information available		information ilable	on	No info	ormation ole	1	-	-	
Ad		n / desorption						***			
Transport		/D coefficient enry's constant	lo	og Kow	E۱	/aporatio	on rate	Method			Note
Soil-water	No availa	information ble	No ir availa	nformatior able		o inform ailable	nation	No information available		n -	
Water-air	No availa	information No information available				o inform ailable	ation	on No information available		n -	
Soil-air	No availa	information ble	No ir availa	nformatior able		o inform ailable	ation	No info		n -	
12.5. Re	esults of	PBT and vPvB asses	ssment	t							
N	o informa	ation available									



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Trading name:	BIO-DIFF 2 RTU REAGENT					
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12.6.	Endocrine disrupting properties					
	No known endocrine disrupting pro	perties 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.	erson authorized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste designations a	ccording to Law:				
	No information available					
13.1.3.	Waste treatment – relevant inform	ation:				
	No information available					
13.1.4.	Sewage disposal – relevant inform					
	Waste must not be disposed of in	to 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 (ADI	R)				
UN num	nber: N	ot subject to transport regulations.				
UN prop	per shipping name: -					
Transpo	ort hazard class(es):					



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	BIO-DIFF 2 RTU REAGENT				
Product code:	BD2-RTU	Date of compilation: 14 November 2022	Version: 4		
Packing group:		-			
Environmentally haz		-			
Special precautions		-			
<u> </u>	ng/shipment by ra	Ţ			
UN number:		Not subject to transport regulations.			
UN proper shipping	ı name:	-			
Transport hazard cla	ass(es):	-			
Packing group:		-			
Environmentally haz	zardous:	-			
Special precautions	for user:	-			
Inland wate	erway transport (A	ADN)			
UN number:		Not subject to transport regulations.			
UN proper shipping	name:	-			
Transport hazard cla	ass(es):	-			
Packing group:		-			
Environmentally haz	zardous:	-			
Special precautions	for user:	-			
Transportir	ng/shipment by se	ea (IMDG)			
UN number:		Not subject to transport regulations.			
UN proper shipping	ı name:	-			
Transport hazard cla	ass(es):	-			
Packing group:		-			
Environmentally haz	zardous:	-			
Special precautions	for user:	-			
Transportir	ng/shipment by a	ir (ICAO-TI/IATA-DGR)			
UN number:		Not subject to transport regulations.			
UN proper shipping	ı name:	-			
Transport hazard cla		-			
Packing group:		-			
Environmentally haz	zardous:	-			
Special precautions		-			
· · · · · · · · · · · · · · · · · · ·					
Further information:	: The produ	uct is not subject to classification.			



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

15.1.	Safety, health and enviror	nmental regulations/legislation specific for the substance or mixture
	EU regulations	
	Authorization and/or rest	trictions 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)	999/13/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 <sub>50</sub>	Lethal dose, 50%	
		LC <sub>50</sub>	Lethal concentration, 50%	
		STOT-SE	Specific target organ toxicity - single exposure	
16.3.	Key literature references and source of data:	_		



### **SAFETY DATA SHEET**

amended by Regulation (EU) No. 2020/878

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Trading name:	BIO-DIFF 2 RTU REAGENT			
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16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classifi	cation	Classification procedure		
-		-		
16.5.	Relevant H statements (number and full text)			
	H: -	-		
16.6.	Training advice:	-		
		** "X" in the product code marks different volumes (different packagings of the product)		
16.7.	Further information:	We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

ANNEX: Exposure scenario resulting to Chemical safety assessment



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

SECTI	ON 1: Identification of	the substanc	e/mixture a	nd of the company/undertaking		
1.1.	Product identifier					
	Trading name:	BIO-DIFF 3	BIO-DIFF 3 RTU REAGENT			
	Chemical name:	-	-			
	Catalogue number:	BD3-RTU	BD3-RTU			
1.2.	Relevant identified use	s of the substance or mixture and uses advised against				
	Uses:		Buffered blue component of Bio-Diff RTU kit.			
	Uses advised against:		Only the identified uses are advised.			
	Reason why uses advi	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: Bio0		oGnost Ltd.			
	Address:		Medjugorska 59, Zagreb			
	Telephone number: Fax no.:		+385 1 2409997			
			+385 1 2404039			
	e-mail of competent person: <u>m</u>		msds@biognost.hr			
	National contact:	-				
1.4.	Emergency telephone number					
	National Protection ar	National Protection and Rescue Dire		112		
	Medical information:			+385 1 2348 342		
	Other information:			_		

SECTION 2. Hazards identification			
2.1.	Classification of the substance or mixture		
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)		
	Hazard class and category code:		Hazard statements*:
	Not identified as hazardous substance.		-
2.1.2.	Additional information		
	-		
*For fu	ll text of Hazard- and EU Hazard-si	tatements: see S	Section 16
2.2.	Label elements		
	Product identification:	BIO-DIFF 3 R	RTU REAGENT
	Identification number:	-	
	Authorization no.:	-	
	Hazard pictograms:	-	



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Trading name:		BIO-DIFF 3 RTU REAGENT					
Product code: BD3-RTU		Date of compilation:	14 November 2022	Version: 6			
Signal wor	Signal word:						
Hazard sta	Hazard statements:						
Precautionary statements:		-					
Supplemetal hazard information							

# 2.3. Other hazards Endocrine Disrupting Properties: No known endocrine disrupting properties.

(EU):

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

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



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Trading name:	BIO-DIFF 3 RTU REAGENT						
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	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.				
4.3.	Indication of any immediate	tion of any immediate medical attention and special treatment needed				
	-					

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

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



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

SECTIO	ON 7. Handling and storage					
7.1.	Precautions for safe handling					
7.1.1.	Protection measures					
	Measures to prevent fire:		Keep away from sources of heat and ignition. Do not smoke.			
	Measures to prevent aerosol and dust generat	ion:	Secure proper ventilation.			
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.			
	Other measures:		-			
7.1.2.	Advice on general occupational hygiene:					
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.					
7.2.	Conditions for safe storage, including any inco	ditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in ventilated storage rooms, and away from sources sunlight, and other incompatible substances.				
	Packaging materials:	Manı	ufacturer's original packaging.			
	Requirements for storage rooms and vessels:		away from food and drink. Keep the containers ly closed.			
	Advices for storage equipment:	The storage must be made of hard material; floors mube resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.				
	Further information on storage conditions:	and o	ot place the unused material in the storage room do not use empty containers for storing other nicals. Do not store with incompatible materials (see on 9).			
7.3.	Specific end use(s)					



Soil (agricultural)

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

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Product code:	BD3-RT	Ū	Date o	of com	npilation: 14 November 2022		ber 2022	Version:	6
Recomme	ndations:				-				
Industrial	sector spe	cific solution	ns:		-				
SECTION 8. Expos	ure contr	ols/persona	l protec	tion					
8.1. Control pa	rameters		-						
:				Occup	ational ex	posure limit			
Substance		CAS N	No			erm values	Biolog	gical limit valu	ies
				pp	om	mg/m³			
-		-			-	-	No informa	tion available	
		•		•	1				
Substance									
name:									
EC No: -		CAS No:	-						
DNEL									
				Indu	strial				
Acute Acute		Acute	Acute			Chronic		Chronic	2
Route of exposure:	effe	ect local	t local effect sys		mic	c effect local		effect syste	emic
Oral	-		-			-			
Inhalation	-		-			-	-		
Dermal	-		-			-	-		
Critical physical par	ameters:	solubility, fla	mmabilit	ty, corro	sivity:	-			
				Cons	umer				
5	,	Acute		Acute		Chron	iic	Chronic	2
Route of exposure:	effe	ect local	effe	ect syste	mic	effect lo	ocal	effect syste	emic
Oral	-		-			-	-		
Inhalation	-		-			-	-		
Dermal	-		-			-	-		
PNEC									
Environmental prot	ection tar	get		I	PNEC				
Fresh water				ı	No information available				
Freshwater sediments				1	No information available				
Marine water					No information available				
Marine sediments					No information available				
Food chain					No information available				
	sewage tr	eatment			No information available				
Microorganisms in sewage treatment					ino information available				

No information available



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Air			No information available				
8.2.	Evaccura controls						
	Exposure controls  Appropriate apping controls						
8.2.1.	Appropriate engineering		S				
	Substance/mixture relate measures to prevent exp during identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.				
	Structural measures to preserve:	revent	No information available				
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.				
	Technical measures to prexposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.				
8.2.2.	Personal protection equi	pment					
8.2.2.1.	Eye and face protection:	n: Safety glasses that stick to face (preventing splashing) (E visor.					
8.2.2.2.	Skin protection						
	Hand protection:		otective 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				
	Other skin protection:		r antistatic clothing made of natural fibers (such as cotton) with long res (EN 13034), and shoes that cover the entire foot (EN 10335).				
8.2.2.3.	Respiratory protection:	filter f	octive 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 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 pr exposure:	event	See Section 6				

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



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Trading name:		<u>-</u>	
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	Value	Method	
Physical state:	liquid	No information available	
Color:	blue	No information available	
Odour/odour threshold:	no odor/no information available	No information available	
Melting point / freezing point:	No information available	No information available	
Boiling point or initial boiling point and boiling range:	No information available	No information available	
Flammability:	No information available	No information available	
Lower and upper explosion limit:	No information available	No information available	
Flash point:	No information available	No information available	
Auto-ignition temperature:	No information available	No information available	
Decomposition temperature:	No information available	No information available	
рН:	6.3 – 7.3	No information available	
Kinematic viscosity:	No information available	No information available	
Solubility:	No information available	No information available	
Partition coefficient n-octanol/water (log value):	No information available	No information available	
Vapour pressure:	No information available	No information available	
Density and/or relative density	No information available	No information available	
Relative vapour density:	No information available	No information available	
Particle characteristics:	No information available	No information available	

SECTIO	SECTION 10.: Stability and reactivity				
10.1.	Reactivity:	See subsections 10.3 through 10.5.			
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.			
10.3.	Possibility of hazardous reactions:	No information available.			
10.4.	Conditions to avoid:	No information available.			
10.5.	Incompatible materials:	No information available.			
10.6.	Hazardous decomposition products:	No information available.			

### **SECTION 11. Toxicological information**



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		1.6. 1: 5	1 · · · (50) 11 · 10-1	70 (0000		
11.1. Informatio	n on hazard classes as	defined in Reg	ulation (EC) No 12	72/2008		
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure 1	time	Results
Oral exposure:	No information available	-	LD <sub>50</sub>	-		-
Dermal exposure:	No information available	-	LD <sub>50</sub>	-		-
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-		-
Specific ta	rget organ toxicity – sir	ngle exposure (	(STOT SE):			
	3 3	c effects		t organ		Note
Oral exposure:	No information a		No information		-	
Dermal exposure:	No information a	vailable	No information	No information available -		
Inhalation exposure	: No information a	vailable	No informati	No information available -		
· · · · · · · · · · · · · · · · · · ·	i i				1	
Aspiration	hazard:	No info	rmation available			
<u> </u>						
Irritation a	nd corrosion:					
:	Exposure time	Species	Evaluation	Method		Note
Skin irritation:	-	rabbit	-			
Eye irritation:	_	rabbit	_			
<u>, ,</u>	!					
Sensitization	on					
Dermal exposure:	No information availa	able				
Inhalation exposure:	No information availa	able				
	:					
Symptoms	related to the physical	l, chemical and	toxicological chara	acteristics		
Oral exposure:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.					
Dermal exposure:		•	sure, resorption effe ingling sensation o		ely. Lon	g-term exposure



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coughing coughing coughing pirect ey			halation of large amounts of vapors in inadequately ventilated perimeter may cause oughing, sneezing, headache and nausea.					
		Direct eye co	rect 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 informatio available	n -
Subchronic oral	No avail	information able	No information available	No informati available	on	No information available	No informatio available	n -
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 informatio available	n -
Chronic oral	No avail	information able	No information available	No informati available	on	No information available	No informatio available	on -
Chronic dermal	No avail	information able	No information available	No informati available	on	No information available	No informatio available	on -
Chronic inhalation	No avail	information able	No information available	No informati available	on	No information available	No informatio available	on -
Chasiti-	tarcat	organ tavisit	v ropostad -	vnocure (C	TOT P	)E).		
Specific	target	1	y – repeated e pecific effects	xposure (S	IOIR		an	Note
Subacute oral			tion available		Target organ  No information available -		-	
Subacute dermal			tion available			nformation avai		-
Subacute inhalat			tion available			nformation avai		_



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

Subchro	onic oral	No informat	ion available	No information available	-			
Subchro	onic dermal No information		ion available	No information available	_			
Subchro	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	inhalation	No informat	ion available	No information available	-			
	1							
	CMR effects (c	arcinogenicity;	mutagenicity; repr	oductive toxicity)				
	Carcinogenicit	y:	Current studies	Current studies on test animals did not indicate carcinogenic effects.				
	Mutagenicity i	n-vitro:	Current <i>in vitr</i>	Current in vitro tests did not indicate mutagenic effects.				
	Genotoxicity:		No information	No information available				
	Mutagenicity i	n-vivo:	Current <i>in vivo</i>	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 or organs.	No toxicity on reproductive organs was determined in reproductive organs.				
	Summary of ev	valuation of the	e CMR properties:	-				
	.i							
11.2.	Information or	other hazard	5:					
11.2.1.	Endocrine disr	upting propert	ies:					
	No known end	locrine disrupt	ing properties that	affect human health.				
11.2.2.	Other information	tions:						

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

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



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

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

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

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

12.3. Bio	12.3. Bioaccumulative potential						
Oct	anol-water partition	coefficient	(log Ko	ow)			
Value	Concentration	рН	°C	Method	Evaluation	Note	
-	No information available	-	-	No information available	No information available	-	
Bio	Bioconcentration factor (BCF)						
Value	Spec	ies		Method	Evaluation	Note	



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Produc	g name:				BIO-D	IFF 3 F	RTU REA	AGENT				
Product code: BD3-RTU  No information No information available available			Date of compilation:		14 November 2022 V		ersion:	6				
			nformation	nation No informati available		n	No information available			No information available		n
	Chronic e	cotoxicity										
	Value	-	150	posure	Spe	ecies	Met	hod	Eva	aluation		Note
Chronic	toxicity on	fish LC <sub>50</sub>	No info	time ormation ilable	No inforn availa	nation ble	No informa availab		No information available		_	
	toxicity on ea ( <i>Daphnic</i>	: <b>F</b> (		rmation ilable	No inforn availa	nation ble	No informa availab		_			
12.4.	Mobility in	n soil predicted dis	tribution in	environm	iental c	ompart	ments:					
		ation availabl	e									
	Surface te		-						1			
	Value No information	°C No	(	Concentra			Method formation ble		Note			
	available		ion	o informa <sup>.</sup> vailable	tion	No inf availab		1	-			
		on informat	ion		tion			1	-			
	available	on informat	av		tion				-			
Transpo	Adsorptio	on informat available	av				ole		- ethod		No	ote
	Adsorptio Ort H	n / desorption A/D coefficient enry's constar	ation No	vailable	Ev	availak	on rate		ethod	on -	No	ote
Soil-wat	Adsorptio  ort H  ter No availa	n / desorption A/D coefficient enry's constar information	ation No avai	vailable log Kow	Evon No	availak aporati	on rate	Me No info	ethod ormatic le	-	Nc	ote
Transpo Soil-wat Water-a Soil-air	Adsorption H ter No available	n / desorption A/D coefficient enry's constar information able information inf	ation No avai	log Kow informatic lable informatic	Evon No ava	aporati o informailable	on rate nation	Mo No info availab	ethod ormatic le ormatic le	on -	Nc	ote
Soil-wat	Adsorption Ort H ter No available No available	n / desorption A/D coefficient enry's constar information able information inf	ation No avai	log Kow informatic lable informatic lable informatic	Evon No ava	aporati o informailable o informailable o informailable	on rate nation	No info availab No info availab No info	ethod ormatic le ormatic le	on -	No	ote



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

12.6.	Endocrine disrupting properties					
	No known endocrine disrupting prop	erties that affect the environment.				
12.7.	Other adverse effects					
	No adverse effects are expected.					
SECTIO	N 13. Disposal considerations					
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
	Submit for disposal to the legal per Protection.	son authorized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste designations ac	ccording to Law:				
	No information available					
13.1.3.	Waste treatment – relevant informa	ition:				
	No information available					
13.1.4.	Sewage disposal – relevant informa					
	Waste must not be disposed of into	o the sewage system.				
13.1.5.	Other disposal recommendations:					
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.					
13.1.6.	Relevant Community provisions:					
	-					
SECTIO	SECTION 14. Transport information					
	Transporting/shipment by road (ADR	)				
UN num	nber: No	t subject to transport regulations.				
UN prop	per shipping name: -					
Transpo	ort hazard class(es):					



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Product code:         BD3-RTU         Date of compilation:         14 November 2022         Version:         6           Packing group:         =	Trading name:	BIO-DIFF 3 RTU REAGENT				
Environmentally hazardous:  Special precautions for user:    Transporting/shipment by rail (RID)	Product code:	BD3-RTU	Date of compilation: 14 November 2022 Version: 6			
Environmentally hazardous:  Special precautions for user:    Transporting/shipment by rail (RID)						
Special precautions for user:         -           UN number         Not subject to transport regulations.           UN proper shipping name:         -           Transport hazard class(es):         -           Packing group:         -           Environmentally hazardous:         -           Special precautions for user:         -           Inland waterway transport (ADN)         Not subject to transport regulations.           UN proper shipping name:         -           Transport hazard class(es):         -           Packing group:         -           Environmentally hazardous:         -           Special precautions for user:         -           UN number         Not subject to transport regulations.           UN number shipping name:         -           Transporting/shipment by sea (IMDG)           UN number shipping name:         -           Transporting/shipment special precautions for user:         -           Packing group:         -           Environmentally hazardous:         -           Packing group:         -           Environmentally hazardous:         -           Packing group:         -           Environmentally hazardous:         -           Packi			-			
UN number shipping name: Transport hazard class(es): Packing group: Inland waterway transport (ADN) UN number shipping name:  Not subject to transport regulations.  Poecial precautions for user: Inland waterway transport (ADN) UN number Not subject to transport regulations.  UN proper shipping name: Inansport hazard class(es): Packing group: In a Packing group: I	Environmentally ha	zardous:	-			
UN n roper shipping name: Transport hazard class(es): Packing group: Environmentally hazardous: Speci precautions for user:  Inland waterway transport (ADN)  UN n roper shipping name:  Fransport hazard class(es):  Packing group: Inland waterway transport (ADN)  UN nuber shipping name:  Fransport hazard class(es):  Packing group:  Environmentally hazardous:  Speci precautions for user:  Packing group:  Fransporting/shipment by sea (IMDG)  UN nuber shipping name:  Transport hazard class(es):  Packing group:  Inland waterway transport (ADN)  Speci precautions for user:  Packing group:  Inland waterway transport (ADN)  Not subject to transport regulations.  Packing group:  Inland waterway transport (ADN)  Not subject to transport regulations.  Packing group:  Inland waterway transport regulations.  Not subject to transport regulations.  Packing group:  Inland waterway transport regulations.  Not subject to transport regulations.	Special precautions	for user:	-			
UN proper shipping name:  Transport hazard class(es): Packing group: Environmentally hazardous: Special preductions for user: Inland waterway transport (ADN) UN number shipping name: UN proper shipping name: Special preductions for user:  Inland waterway transport (ADN) UN proper shipping name:  Transport hazard class(es): Packing group: Inland waterway transport (ADN)  UN number shipping name: Inland waterway transport (ADN)  UN number shipping name: Inland waterway transport (ADN)  Inlan	Transporti	ng/shipment by rail	(RID)			
Transport hazard class(es):         -           Packing group:         -           Environentally hazardous:         -           Special preductions for user:         -           Inland waterway transport (ADN)         Not subject to transport regulations.           UN proper shipping name:         -           Transport hazard class(es):         -           Packing group:         -           Environentally hazardous:         -           Special preductions for user:         -           Inansporting/shipment by sea (WDG)         Not subject to transport regulations.           UN norber shipping name:         -           1 Packing group:         -           Environentally hazardous:         -           Special precautions for user:         -           Special precautions for user:         -           In ansporting/shipment by air (UCO-TI/IATA-DGR)           UN number shipping name:         -           In ansporting/shipment by air (UCO-TI/IATA-DGR)           UN number shipping name:         -           In ansporting/shipment by air (UCO-TI/IATA-DGR)	UN number:		Not subject to transport regulations.			
Packing proup:         -           Envirormentally hazardous:         -           Special precautions for user:         -           Inland waterway transport (ADN)         -           UN number:         Not subject to transport regulations.           UN proper shipping name:         -           Transport hazard class(es):         -           Packing group:         -           Envirormentally hazardous:         -           Special precautions for user:         -           VN number:         Not subject to transport regulations.           UN proper shipping name:         -           Transporting/shipment by sea (IMDG)         -           UN proper shipping name:         -           Transporting/shipment by are (ICDG)         -           Envirormentally hazardous:         -           Special precautions for user:         -           VN number:         Not subject to transport regulations.           UN number:         Not subject to transport regulations.           UN proper shipping name:         -           Transporting/shipment by air (ICDG)           UN number:         Not subject to transport regulations.           UN number:         Not subject to transport regulations.           UN proper shipping name:<	UN proper shipping	g name:	-			
Environethally hazardous:         -           Special precautions for user:         -           Inland waterway transport (ADN)         -           UN number:         Not subject to transport regulations.           UN proper shipping name:         -           Transport hazard class(es):         -           Packing group:         -           Environethally hazardous:         -           Special precautions for user:         -           Transporting/shipment by sea (IMDG)           UN number:         Not subject to transport regulations.           UN proper shipping name:         -           Transporting/shipment by air (ICD)         -           Environethally hazardous:         -           Special precautions for user:         -           Transporting/shipment by air (ICD-TI/IATA-DGR)         Not subject to transport regulations.           UN number:         Not subject to transport regulations.           UN proper shipping name:         -           Transporting/shipment:         -           Transporting/shipment:         -           Transporting/shipment:         -           Transporting/shipment:         -           Transporting/shipment:         -           Transporting/shipment:         -	Transport hazard cl	ass(es):	-			
Inland waterway transport (ADN)     UN number:   Not subject to transport regulations.     UN proper shipping name:   -     Transport hazard class(es):   -     Packing group:   -     Environmentally hazardous:   -     Transporting/shipment by sea (IMDG)     UN number:   Not subject to transport regulations.     UN proper shipping name:   -     Transporting/shipment by sea (IMDG)     UN number:   Not subject to transport regulations.     UN proper shipping name:   -     Transporting/shipment by air (ICAO-TI/IATA-DGR)     UN number:   Not subject to transport regulations.     Un proper shipping name:   -     Transporting/shipment by air (ICAO-TI/IATA-DGR)     UN number:   Not subject to transport regulations.     UN proper shipping name:   -     Transport hazard class(es):   -     Packing group:   -     Environmentally hazardous:   -     Packing group:   -     Environmentally hazardous:   -     Special precautions for user:   -	Packing group:		-			
Inland waterway transport (ADN)  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 (IMDG)  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 air (ICAO-TI/IATA-DGR)  UN number: Not subject to transport regulations.  UN proper shipping name: - Transport hazard class(es): - Packing group: - Environmentally hazardous: - Special precautions for user: -  Transport hazard class(es): - Packing group: - Environmentally hazardous: - Special precautions for user: -  Environmentally hazardous: - Special precautions for user: -	Environmentally ha	zardous:	-			
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UN proper shipping name:  Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  Transporting/shipment by sea (IMDG)  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 air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  -  Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  UN proper shipping name:  -  Transport hazard class(es):  -  Packing group:  -  Environmentally hazardous:  -  Special precautions for user:  -	Inland wat	erway transport (AD	N)			
Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  Transporting/shipment by sea (IMDG)  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 air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  UN proper shipping name:  - Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number:  UN proper shipping name:  - Transport hazard class(es):  Packing group:  Environmentally hazardous:  - Special precautions for user:  -  Fransport hazard class(es):  -  Packing group:  Environmentally hazardous:  -  Special precautions for user:  -	UN number:		Not subject to transport regulations.			
Packing group:  Environmentally hazardous:  Special precautions for user:  Transporting/shipment by sea (IMDG)  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 air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  UN proper shipping name:  - Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  UN proper shipping name:  - Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  -  Environmentally hazardous:  -  Special precautions for user:  -	UN proper shipping	g name:	-			
Environmentally hazardous:  Special precautions for user:  Transporting/shipment by sea (IMDG)  UN number: Not subject to transport regulations.  UN proper shipping name: - Transport hazard class(es): - Racking group: - Environmentally hazardous: - Special precautions for user: - Transporting/shipment by air (ICAO-TI//IATA-DGR)  UN number: Not subject to transport regulations.  UN proper shipping name: - Transport hazard class(es): - Racking group: - Environmentally hazardous: - Special precautions for user: -  Facking group: - Environmentally hazardous: - Special precautions for user: -  Environmentally hazardous: - Special precautions for user: -	Transport hazard cl	ass(es):	-			
Special precautions for user:  Transporting/shipment by sea (IMDG)  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 air (ICAO-TI/IATA-DGR)  UN number: Not subject to transport regulations.  UN proper shipping name: - Transport hazard class(es): - Packing group: - Environmentally hazardous: - Special precautions for user:	Packing group:		-			
Transporting/shipment by sea (IMDG)  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 air (ICAO-TI/IATA-DGR)  UN number: Not subject to transport regulations.  UN proper shipping name: -  Transport hazard class(es): -  Packing group: -  Environmentally hazardous: -  Special precautions for user: -  Special precautions for user: -	Environmentally ha	zardous:	-			
UN number: UN proper shipping name:	Special precautions	for user:	-			
UN proper shipping name:  Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  UN proper shipping name:  Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  -  Special precautions for user:  -  Special precautions for user:  -	Transporti	ng/shipment by sea	(IMDG)			
Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  UN proper shipping name:  Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  -  Special precautions for user:  -	UN number:		Not subject to transport regulations.			
Packing group:  Environmentally hazardous:  Special precautions for user:  Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number: Not subject to transport regulations.  UN proper shipping name:  Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  -  -  -  -  -  -  -  -  -  -  -  -  -	UN proper shipping	g name:	-			
Environmentally hazardous:  Special precautions for user:  Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  UN proper shipping name:  Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  -	Transport hazard cl	ass(es):	-			
Special precautions for user:  Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number:  Not subject to transport regulations.  UN proper shipping name:  - Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  -	Packing group:		-			
Transporting/shipment by air (ICAO-TI/IATA-DGR)  UN number: Not subject to transport regulations.  UN proper shipping name: -  Transport hazard class(es): -  Packing group: -  Environmentally hazardous: -  Special precautions for user: -	Environmentally ha	zardous:	-			
UN number:  UN proper shipping name:  Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  Not subject to transport regulations.  -  Special precautions.  Not subject to transport regulations.  -  Special proper shipping name:  -  Special proper shipping name:	Special precautions	for user:	-			
UN proper shipping name:  Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:	Transporti	ng/shipment by air (	(ICAO-TI/IATA-DGR)			
Transport hazard class(es):  Packing group:  Environmentally hazardous:  Special precautions for user:  -	UN number:		Not subject to transport regulations.			
Packing group:  Environmentally hazardous:  Special precautions for user:  -	UN proper shipping	g name:	-			
Environmentally hazardous: - Special precautions for user: -	Transport hazard cl	ass(es):	-			
Special precautions for user: -	Packing group:		-			
	Environmentally ha	zardous:	-			
Further information: The product is not subject to classification.	Special precautions	for user:	-			
Further information: The product is not subject to classification.						
	Further information	n: The product	is not subject to classification.			



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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 restrictions of use						
	Authorizations:	-					
	Restrictions:	-					
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);					
	Information according 19 guideline)	999/13/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 <sub>50</sub>	Lethal dose, 50%		
		LC <sub>50</sub>	Lethal concentration, 50%		
		STOT-SE	Specific target organ toxicity - single exposure		
16.3.	Key literature references and source of data:	_			



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

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

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
Classifi	cation	Classification procedure			
_		-			
16.5.	Relevant H statements (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 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	Product identifier			
	Trading name:	BUFFER SO	LUTION, p	oH 6.8	
	Chemical name:	-			
	Catalogue number:	PUF68-OT-	X**		
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against	
	Uses:		Buffer so	olution for use in hematology, 6 mM.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplier	of the safety	data shee	t	
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb +385 1 2409997 +385 1 2404039 msds@biognost.hr		
	Telephone number:				
	Telefax.:				
	e-mail of competent p	erson:			
	National contact:		-		
1.4	Emergency telephone	Emergency telephone number			
	National Protection ar	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ECTION 2. Hazards identification				
2.1	Classification of the substance	Classification of the substance or mixture			
2.1.1	Classification according to R	egulation (EC) No 1	272/2008 (CLP)		
	Hazard class and cate	egory code:	Hazard statements*:		
	Not identified as hazardous	substance.	-		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazaı	rd-statements: see	SECTION 16		
2.2	Label elements				
	Product identification:	BUFFER SOLUT	ION, pH 6.8		
	Identification number:	number: -			
	Authorization number: -				
	Hazard pictograms:	-			



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

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

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

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

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



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

SECTI	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the substance or mixture				
	Hazardous combustion products:	No information available.			
5.3	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.				
5.4	Additional information				
	Do not contaminate the environment	ent with extinguishing media.			

SECTIO	N 6. Accidental release meas	ures				
6.1	Personal precautions, protective equipment and emergency procedures					
6.1.1.	For non-emergency personnel					
	Protective equipment:	Use personal protective equipment (see Section 8).				
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.				
	Emergency procedures: Mark the area using proper signs.					
6.1.2.	For emergency responders:					
	Use protective equipment; in a (see Section 8).	case of inadequate ventilation use adequate airways protective equipment				
6.2	Environmental precautions:					
	Do not dispose of in sewage, or Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National rate (NPRD) on 112.				
6.3	Methods and material for con-	tainment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.				
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents.				
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).				
6.4	Reference to other sections					



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See Section 7 for information about secure handling.

See Section 8 for information about personal protective equipment.

See Section 13 for information about containment.

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

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



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



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Trading name:		BUFFER SOLUTION	I, pH 6.8		
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	Structural measures to prevent exposure:		In accordance with Section 7.			
	Organisational measures to prevent exposure:		Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent ex	(posure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.			
8.2.2.	Personal protection equipment					
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of low levels of concentration in air; protective gas mask that covers entire face in case of higher levels of concentration in air.				
8.2.2.2. Skin protection						
	Hand protection:	Protective nitrile gloves, 0.11 mm thick (EN 374).				
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.				
8.2.2.3.	Respiratory protection:		adequate ventilation to the premises where the product is and/or handled.			
8.2.2.4.	Thermal hazards:	No info	ormation available			
8.2.3.	Environmental exposure controls					
	Substance/mixture related measures to prevent exposure:	See Se	ection 6			
	Structural measures to prevent exposure:	Use m	odern equipment.			
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the lace.			
	Technical measures to prevent exposure:	See Section 6				

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



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	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	рН:	6.75 – 6.85	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

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

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



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

No

information

available

No information

available

Subacute

inhalation

No

information

available

No

information

available

No

information

available



Reproductive toxicity:

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

No information available



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

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

### 12.2 Persistence and degradability



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



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Product	code:	PUF68-OT-X**	Date	of compila	tion:	22 De	c 2022	Version:	4
	c toxicity on cea ( <i>Daphnia</i> )		No information available	information information informa			No information 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		information ilable				
Transpor	t .	n / desorption  A/D coefficient  enry's constant	log Kow	Evapora	ation rate		Method	Note	<u> </u>
Soil-wate	No.	information	No informatio	•	rmation		nformation		
Water-ai	No	information	No informatio		rmation		nformation	_	
Soil-air	No availa	information able	No informatio available	n No info		No ir	nformation able	-	
12.5.	Results of	PBT and vPvB asse	ssment						
	Based on a	available data, the	product does no	ot contain ar	ny PBT or	vPvB su	ıbstances.		
12.6.	Endocrine	disrupting propert	ies						
	No known	endocrine disrupt	ing properties th	nat affect the	environ	ment.			
12.7.	Other adv	erse effects							
	No advers	e effects are expec	ted.						
SECTION	I 12 Dien	osal consideration							
13.1		osal consideration eatment methods	15						
. 3. 1	Traste ti	outment metrious							



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



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

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



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

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



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

ANNEX: Exposure scenario resulting to chemical safety assessment
-



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

SECTI	ON 1: Identification of	the substance	e/mixture	and of the company/undertaking	
1.1	Product identifier				
	Trading name:	BUFFER SO	LUTION, p	H 7.2	
	Chemical name:	-			
	Catalogue number:	PUF72-OT-X	X**		
1.2	Relevant identified use	es of the subst	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 advis	sed against:	duct is intended for use only as an <i>in vitro</i> diagnostic medical registered at the Agency for Medicinal Products and Medical and there is no reason to use it for other purposes.		
1.3	Details of the supplier	of the safety	data shee	t	
	Supplier:		BioGnost Ltd.		
	Address:		Medjugo	Medjugorska 59, Zagreb	
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2	2404039	
	e-mail of competent p	erson:	msds@b	oiognost.hr	
	National contact:		-		
1.4	Emergency telephone	number			
	National Protection ar	nd Rescue Dire	ectorate:	112	
	Medical information:	ical information:		+385 1 2348 342	
	Other information:			-	

SECTIO	TION 2. Hazards identification					
2.1	Classification of the substance or mixture					
2.1.1	Classification according to Reg	Classification according to Regulation (EC) No 1272/2008 (CLP)				
	Hazard class and categ	ory code:	Hazard statements*:			
	Not identified as hazardous su	bstance.	-			
2.1.2.	Additional information					
	-					
*For fu	ll text of Hazard- and EU Hazard	-statements: see S	ECTION 16			
2.2	Label elements					
	Product identification:	BUFFER SOLUTI	ON, pH 7.2			
	Identification number:	Identification number: -				
	Authorization number: -					
	Hazard pictograms:	-				



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

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

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



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

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

SECTIO	ECTION 6. Accidental release measures						
6.1	Personal precautions, protective equipment and emergency procedures						
6.1.1.	For non-emergency personnel						
	Protective equipment:	Use personal protective equipment (see Section 8).					
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.					
	Emergency procedures: Mark the area using proper signs.						
6.1.2.	For emergency responders:						
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).						
6.2	Environmental precautions:						
	Do not dispose of in sewage, or Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National rate (NPRD) on 112.					
6.3	Methods and material for con-	tainment and cleaning up					
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.					
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents.					
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).					
6.4	Reference to other sections						



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See Section 7 for information about secure handling.

See Section 8 for information about personal protective equipment.

See Section 13 for information about containment.

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

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



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



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

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



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	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	рН:	7.2	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

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

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



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Product code:	Р	UF72-OT-X**		ate of compila	ation: 22 Dec 2022		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:

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Product code.	PU	F72-U1-X***	Da	ate of compila	tion.	22 De	C 2022	VE	ersion. <sup>2</sup>
Subchronic oral	No availa	information able	No information available	No information available	No infor availa	mation able	No information available	on	-
Subchronic No information dermal available		No information available	No information available	No infor availa	mation able	No information available	on	-	
Subchronic No information inhalation available		No information available	No information available	information		No information available	on	-	
Chronic oral	No availa	information able	No information available	No information available	No No information available 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	n available No ir		No information available		-	
Subacute derma		No informa	ation available		No information available		-		
Subacute inhalat	ion	No informa	ation available		No information available		-		
Subchronic oral		No informa	tion available		No in	No information available		-	
Subchronic dern	nal	No informa	ation available	railable		No information available		-	
Subchronic inha	lation		ation available		No information available		-		
Chronic oral			ation available		No information available		-		
Chronic dermal No information as					No information available		-		
Chronic inhalation	on	No informa	ation available		No in	formatio	n available	-	
			y; mutagenicity	y; reproductive					
Carcinogenicity:			No inform						
Mutage	·····	n vitro:		No inform					
Genoto				No inform					
Mutage				No inform					
Germ co	en muta	agenicity:		ino intorm	No information available				

No information available



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

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

#### 12.2 Persistence and degradability



PUF72-OT-X\*\*

Trading name:

Product code:

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



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



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



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

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



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

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

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



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

ANNEX: Exposure scenario resulting to chemical safety assessment	
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