

# SPERM-DIFF RTU KIT

The kit contains:

Sperm-Diff 1 RTU reagent Sperm-Diff 2 RTU reagent Sperm-Diff 3 RTU reagent



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Trade name:	SPERM-DIFF 1 RTU REAGENT					
Product code:	SP1-RTU	Date of compilation:	14 November 2022	Version: 3		

SECTI	ON 1: Identification of the subs	tance/mixture a	nd of the company/undertaking	
1.1.	Product identifier			
	Trade name:	SPERM-DIFF 1	RTU REAGENT	
	Chemical name:	-		
	Catalogue number:	SP1-RTU		
1.2.	Relevant identified uses of the	substance or mix	ture and uses advised against	
	Uses:	Fixative comp	onent of Sperm-Diff RTU kit.	
	Uses advised against:	Only the iden	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 here is no reason to use it for other purposes.	
1.3.	Details of the supplier of the sa	fety data sheet		
	Supplier:	BioGnost Ltd.		
	Address:	Medjugorska	59, Zagreb	
	Telephone number:	+385 1 24099	97	
	Telefax:	+385 1 24040	39	
	e-mail of competent person:	msds@biogno	<u>ost.hr</u>	
	National contact:			
1.4.	Emergency telephone numbers			
	National Protection and Rescue	e Directorate:	112	
	Medical information:		+385 1 2348 342	
	Other information:		-	

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



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Product ic	lentification:	SPERM-DIFF 1 RTU REAGENT
Identificat	ion number:	-
Authorisat	tion number:	-
Hazard pi	ctograms:	GHS02 GHS06 GHS08
Signal wo	rd:	Danger
Hazard sta	atements:	<ul><li>H225 Highly flammable liquid and vapor.</li><li>H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.</li><li>H370 Causes damage to organs (eyes).</li></ul>
Precaution	nary statements:	<ul> <li>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</li> <li>P233 Keep container tightly closed.</li> <li>P280 Wear protective gloves, protective clothing, eye protection, face protection.</li> <li>P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.</li> <li>P302+P352 IF ON SKIN: Wash with plenty of soap and water.</li> <li>P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</li> <li>P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.</li> </ul>
Suppleme informatic		-
2.3. Other haz	ards	
No knowr	e Disrupting Pro	



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SECTION 3. Co	SECTION 3. Composition/information on ingredients						
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)			
67-56-1/ 200-659-6/ 603-001-00-X	01-2119433307- 44-xxxx	95 - 100 %	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 n	neasures			
	General notes:	First aider needs to protect himself.			
	Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration, if necessary also oxygen. In case of irregular breathing or respiratory arrest provide artificial respiration.			
	Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at 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

SECTIO	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 subs	tance or mixture			
	Hazardous by products of fire:	Combustible. Vapours are heavier than air and may spread along floors. Forms explosive mixtures with air at ambient temperatures. Development of hazardous combustion gases or vapours possible in the event of fire.			
5.3.	Advice for firefighters				
	Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.				
5.4.	Additional information				
	Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.				

SECTIO	ION 6. Accidental release measures					
6.1.	Personal precautions, protective equipment and emergency procedures					
6.1.1.	1. For non-emergency personnel					
	Protective equipment:		Use personal protective equipment (see Section 8).			
	Accident prevention methods:		Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.s			
	Emergency procedures		Mark the area using proper signs.			
6.1.2.	For emergency respon	ders:				
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).					
6.2.	Environmental precaut	ions:				
	Do not let product ent	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 sections			
	See Section 7 for information on safe handling.			
	See Section 8 for information on personal protective equipment.			
	See Section 13 for disposal information.			

SECTIO	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	on: 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. The	proughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incom	patibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in 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.	



**Recommendations:** 

Industrial sector specific solutions:

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

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Further information on storage conditions:		and d chem	ot place the unused mate o not use empty contain icals. Do not store with ir ection 10).	ers for storing of	ther
7.3. Specific	nd use(s)				

-

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SECTION 8. Expos	ure contr	ols/persona	l protec	tion			
8.1. Control pa			in protec				
Substance		CAS No		Occupational exposure limit values/short term values		Biological limit values	
				ppm	mg/m <sup>3</sup>		
Methanol		67-56	5-1	200	260	(7.0 mg/	nol/mol of creatinine* /g of creatinine*), shift urinary excretion
* For all results per consideration	taining cre	eatinine leve	ls, creatiı	nine concentrati	on < 0.5 g/l and	d > 3.0 g/	l may not be taken into
Substance: -							
EC No: -		CAS No:	-				
DNEL							
				Industrial			
Route of		Acute	Acute		Chronic		Chronic
exposure:	effe	ect local	effect systemic		effect local		effect systemic
Oral	-		-		-		-
Inhalation	260 m (metha	5	260 mg/m <sup>3</sup> (methanol)		260 mg/m <sup>3</sup> (methanol)		260 mg/m <sup>3</sup> (methanol)
Dermal	-		40 mg/kg (methanol)				40 mg/kg (methanol)
Critical physical pa	ameters:	solubility, fla	mmabili	ty, corrosivity:	•	_	
				Consumer			
Route of		Acute		Acute	Chron	ic	Chronic
exposure:	effe	ect local	effe	ect systemic	effect local		effect systemic
Oral	-		8 mg/k	g (methanol)	-		8 mg/kg (methanol)
Inhalation	50 mg		50 mg/m <sup>3</sup>		50 mg/m <sup>3</sup>		50 mg/m <sup>3</sup>
(me		anol)	(metha	nol)	(methanol)		(methanol)
Dermal -			8 mg/k	g (methanol)			8 mg/kg (methanol)
PNEC							



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Environmental protection target	PNEC	
Fresh water	154 mg/l (methanol)	
Freshwater sediments	570.4 mg/kg (methanol)	
Marine water	15.4 mg/l (methanol)	
Marine sediments	No information available	
Food chain	No information available	
Microorganisms in sewage treatment	100 mg/l (methanol)	
Soil (agricultural)	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:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to prevent exposure:	No information available			
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).			
8.2.2.2.	Skin protection:	1			
		The protective gloves to be used must comply with the specification of EC Directive 2016/425 and the related standard EN374. Full contact:			
		Glove material: butyl rubber			
	Hand protection:	Glove thickness: 0.70 mm			
		Break through time: > 480 min			
		Splash contact:			
		Gloves material: viton (R)			
		Glove thickness: 0.70 mm			
		Break through time: >120 min			



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Trade name:       Product code:       SP1-RTU       Da         Other skin protection:       Other skin protection:       Da		SPERM-DIFF 1 RTU REAGENT					
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		skin protection:		The type of pro the concentrat	tatic suit protecting again otective equipment must b ion and amount of the c rkplace and shoes that co	be selected a dangerous s	according to substance a
			Required when vapours/aerosols are generated. Recommended filter type: gas filter AX colour code brown (EN 371). The				

8.2.2.3.	Respiratory protection:	filter type: gas filter AX, colour code brown (EN 371). The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment. Do not let product enter drains. Risk of explosion.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

.1.	Information on basic physical and	chemical properties	
		Value	Method
	Physical state:	liquid	No information available
	Colour:	light blue	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	Ignition temperature: 455 °C		

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

SECTION 11. To	SECTION 11. Toxicological information						
11.1. Informa	tion on hazard classes as	defined in Regula	ation (EC) No 1272	/2008			
Acute to	oxicity:						
Route of exposure:	Method Species LD <sub>50</sub> /LC <sub>50</sub> or Results						
Oral:	No information available	rat	LD <sub>50</sub>	-	125.13 mg/kg (methanol)		
Dermal:	No information available	rabbit	LD <sub>50</sub>	-	375.13 mg/kg (methanol)		



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Trade name:		SPERN	1-DIFF 1 RTU	REAGENT			
Product code:	SP1-RTU	Date of compile	ation: 14 N	lovember 202	2 Version: 3		
Inhalation:	No information available	rat ICro Ab		3.88 mg/l (methanol)			
Specific	target organ toxicity -	single exposure (S	TOT-SF):				
	Specific	<u> </u>		et organ	Note		
Oral:	No information avail		No informati	5	-		
Dermal:	No information avail	able	No informati	on available	-		
Inhalation:	No information avail	able	Eyes		mixture causes damage to organs		
Aspiratic	on hazard:	No inforr	nation available				
Irritation	and corrosion						
	Exposure tim	e Species	Evaluation	Method	Note		
Skin corrosion/irritatio	n -	-	-	-	drying-out effect resulting in rough and chapped skin		
Serious eye damage/irritation	-	-	-	-	irritations of mucous membranes		
_							
Sensitiza							
Skin sensitization: Respiratory sensitization:	Does not cause						
sensitization.							
Symptor	ns related to the physi	cal, chemical and t	oxicological cha	aracteristics:			
Oral exposure:	Stomach and bowel abdominal pain. Abs		• •	5	unwell, vomiting, strong kidney, cardiac.		
Dermal exposure:	Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.						
Inhalation exposure:	Airways irritation and possible lung damage due to high levels of vapor concentration, dizzindrowsiness, headache. Absorption may cause toxic effects.						
Eye exposure:	Mild to moderate irri cornea damage,blinc occur later, after the	lness, irreversible d	•		, lesser possibility of isual impairments may		
Reneated	d dose toxicity (subacu	ite, subchronic, chr	onic)				
repeater	Dose Ex				Evaluation Note		



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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 <i>in-vivo</i> :	No information available				
	Germ cell mutagenicity:	No information available				
	Reproductive toxicity:	No information available				
	Summary of evaluation of the CMR properties:	No information available				
11.2.	Information on other hazards:					
11.2.1.	Endocrine disrupting properties:					
	No known endocrine disrupting properties that affect human health.					
11.2.2.	Other information:					
	-					

SECTION 12. Ecological information								
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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Product code	:	SP1-RTU	Da	ate of c	ompilation:	14 N	lovemb	er 2022	Vei	rsion:	3
Crustacea:		EC <sub>50</sub>	48 hours	No in availa	formation able	information info		No informa availabl			
Algae/aquatic plants:		IC <sub>50</sub>	72 hours	No in availa	formation able	No infor avail	mation able	No informa availabl		-	
Other organisr	ns	-	-	-		-		-		-	
		and degrad	ability								
Abiot		adation	alf lives		Method			Evalu	ation		Nata
Marine water		egradation l Iformation a		No in	Information avai	labla	Noir	Iformatio		ilabla	Note -
Fresh water		formation a			formation avai						-
Air		formation a			formation avai				ation available ation available		-
Soil		formation a			formation avai				tion available		_
5011	NO II					lable	NO II	nonnatio	11 ava	liable	
Biode	gradat	ion									
% Degradatio	on	Time (d	ays)	Ν	/lethod		Evaluatic	n		Not	e
-		-	-			No ir availa	nformatio able		-		
12.3. Bioac	cumula	ative potent	ial								
			coefficient	(log Kov	N)						
Value	Conc	entration	рН	°C	Method		Evalua	ation		No	ote
_	No i availab	nformation le	-	-	-	No informatic available		ation	-		
Bioco	ncentr	ation Factor	· (BCF)								
Value		Spe	cies		Method	Evaluation			No	te	
No informatioı available		No informat available	ion	No information No information available available		on	No information available				



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	Va	lue	Dose	Exposure time		Species	Me	thod Eva		ation	Note		
Chronic	c toxic	ity on fish	LC <sub>50</sub>	No information available		o formation vailable	No inform availal		No inforr available	nation	-		
Chronic crustac			EC <sub>50</sub>	No information available		o formation vailable	No inform availal		No inforr available	nation	-		
12.4.	Mol	pility in soil											
	Kno	wn or predicte	d distributi	on in enviro	nmen	tal compartn	nents:						
	No	information av	ailable										
	Surf	ace tension:											
		Value	c	°C		Concentrati	on		Method		Note		
	No avai	information lable	No ir available	nformation	No ir	nformation a	available No information a		No information available		No information available		-
Transpo	I	orption / deso A/D coeff Henry's cc	icient	log Ko	w	Evaporatio	n rate	M	ethod	Nc	ote		
Soil-Wa	ater	No in available	formation	No inform available	ation	No informa available	ation	No info availabl	rmation e	-			
Water-	Air	No in available	formation	No inform available	ation	No informa available	ation		No information				
Soil-Air	~	No in available	formation	No inform available	ation	No informa available	ation	No information available		-			
12.5.	Res	ults of PBT and	vPvB asses	ssment									
	Sub	stance(s) in the	e mixture d	o(es) not me	eet the	e criteria for	PBT or vl	PvB					
12.6.	End	ocrine disrupti	ng properti	ies									
	acco	substance/mix ording to REAC ulation (EU) 20	H Article 5	7(f) or Com	nissior	n Delegated					•		



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Trade name:									
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	verse effects rse effects are exp	ected.							
SECTION 13. Dis	posal considerati	ons							
13.1. Waste	treatment method	eatment methods							

13.1.1. Product/Packaging disposal:

Waste material must be disposed of according to the national and local rules and regulations. Do not mix with other sorts of waste. Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2. Waste codes/waste designations according to Law:

No information available

13.1.3.

15 01 10\*: packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

Waste codes/waste designations according to Low:

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 according to official regulations.

#### SECTION 14. Transport information

Transporting/shipment by road (ADR)			
UN number:	1230		
UN proper shipping name:	Methanol		
Transport hazard class(es):	3 (6.1)		
Packing group:	II		
Environmental hazards:	-		
Special precautions for user:	-		



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Trade name:	SPERM-DIFF 1 RTU REAGENT				
Product code:	SP1-RTU	Date of compilation:	14 November 2022	Version:	3

Transporting/shipment by rail (R	ID)
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	П
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:	11
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:	11
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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	Authorisations and/or res	trictions on use
	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	<ul> <li>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/9. and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</li> <li>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organi solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</li> <li>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 10 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</li> <li>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</li> </ul>
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessme	ent
	None	

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



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

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Trade name:	SPERM-DIFF 1 RTU REAGENT			
Product code:	SP1-RTU	Date of compilation:	14 November 2022	Version: 3

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)				
Classifi	cation		Classification procedure		
-			-		
16.5.	Relevant H statements (num		ber and full text)		
		225	Highly flammable liquid and vapor.		
	H:	301+311+331	Toxic if swallowed, in contact with skin or if inhaled.		
		370	Causes damage to organs (eyes).		
16.6.	Trai	ning advice:	-		
16.7.	Further information:				<ul> <li>** "X" in the product code marks different volumes (different packaging of the product)</li> <li>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</li> </ul>

ANNEX: Exposure scenario resulting to Chemical safety assessment



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Trading name:	SPERM-DIFF 2 RTU REAGENT				
Product code:	SP2-RTU	Date of compilation:	14 November 2022	Version:	3

SECTI	ON 1: Identification of	the substanc	e/mixture a	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	SPERM-DIFF 2 RTU REAGENT		AGENT	
	Chemical name:	-			
	Catalogue number:	SP2-RTU			
1.2.	Relevant identified use	es of the subs	stance or mi	xture and uses advised against	
	Uses:		Red comp	onent of Sperm-Diff RTU kit.	
	Uses advised against:		Only the i	dentified uses are advised.	
	Reason why uses advis	n why uses advised against: device, registered at t		ict is intended for use only as an <i>in vitro</i> diagnostic medical gistered at the Agency for Medicinal Products and Medical nd there is no reason to use it for other purposes	
1.3.	Details of the supplier of the safety data sheet				
	Supplier: Bi		BioGnost Ltd.		
	Address: N		Medjugorska 59, Zagreb		
	Telephone number: +		+385 1 2409997		
	Fax no.: +		+385 1 2404039		
	e-mail of competent person: m		<u>msds@biognost.hr</u>		
	National contact:	-	-		
1.4.	Emergency telephone	number			
	National Protection ar	nd Rescue Dir	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:	Other information:		-	

SECTIO	SECTION 2. Hazards identification				
2.1.	Classification of the substance or mixture				
2.1.1.	Classification according to Regula	tion (EC) No 12	272/2008 (CLP)		
	Hazard class and category	code:	Hazard statements*:		
	Not identified as hazardous subst	ance.	-		
2.1.2.	Additional information				
	-				
*For ful	text of Hazard- and EU Hazard-sta	itements: see S	Section 16		
2.2.	Label elements				
	Product identification:	SPERM-DIFF	2 RTU REAGENT		
	Identification number:	-			
	Authorization no.:	-			
	Hazard pictograms:	-			



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Trading name:	SPERM-DIFF 2 RTU REAGENT			
Product code:	SP2-RTU	Date of compilation:	14 November 2022	Version: 3

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

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

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



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				5
Trading name:		SPERM-DIFF 2	2 RTU REAGENT	
Product code	SP2-RTU	Date of compilation:	14 November 2022	Version: 3
Follow	Swallowing may cause irritation of mucosa, tingling sensation in the 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.		cause nausea, piration causes	
4.3. Indica	tion of any immedi	n of any immediate medical attention and special treatment needed		
-				

\_\_\_\_\_

SECTIO	SECTION 5. Firefighting measures			
5.1.	Extinguishing media	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.			

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



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Trading r	ame:	SPERM-DIFF 2 RTU REAGENT		
Product o	ode:	SP2-RTU Date of compilation: 14 November 2022 Version: 3		Version: 3
6.3.2. Cleaning up: Where possible, the substance can be absorbed by using inflammable ventilated storage rooms until disposal. Submit for disposal to the lect		e the waste material Ibstance in well		

		persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.	
6.3.3.	Other information:	-	
6.4.	Reference to other sections		
	See Section 7 for information about secure handling.		
	See Section 8 for information about personal protective equipment.		
	See Section 13 for information about containment.		

SECTIO	ON 7. Handling and storage			
7.1.	Precautions for safe handling			
7.1.1.	Protection measures			
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.		
	Measures to prevent aerosol and dust generation	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.	7.2. Conditions for safe storage, including any incompatibilities			
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.		
	Packaging materials:	Manufacturer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.		
Advices for storage equipment: be resistant to chemicals. There must directly leads into sewage system. See		The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.		
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).		
7.3.	Specific end use(s)			



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	1			<u>i</u>

Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposur		ois/persona	ii protec	uon				
8.1. Control para	meters			Осси	pational	exposure limit		
Substance		CASI	No			term values	Biological limit valu	ies
				р	pm	mg/m <sup>3</sup>		
-		-			-	-	No information available	
Substance _ name: _								
EC No: -		CAS No:	-					
DNEL						L		
				Ind	ustrial			
Pouto of overagives	ļ	Acute		Acute	9	Chror	nic Chronie	2
Route of exposure:	effe	ect local	effe	ect syst	emic	effect lo	ocal effect syste	emic
Oral	-		-			-	-	
Inhalation	-		-			-	-	
Dermal	-		-			-	-	
Critical physical parar	neters: s	solubility, fla	immabilit	ty, corr	osivity:	-		
			1	Con	sumer			
Route of exposure:		Acute		Acute	•	Chror		2
Noute of exposure.	effe	ect local	effe	ect syst	emic	effect lo	ocal effect syste	emic
Oral	-		-			-	-	
Inhalation	-		-			-	-	
Dermal	-		-			-	-	
PNEC								
Environmental protect	tion tar	get			PNEC			
Fresh water					No infor	mation availab	le	
Freshwater sediments	5					mation availab		
Marine water					No infor	mation availab	le	
Marine sediments					No infor	mation availab	le	
Food chain					No infor	mation availab	le	
Microorganisms in se	wage tr	eatment			No infor	mation availab	le	
Soil (agricultural)				Ī	No infor	mation availab	le	



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Trading name:		SPERM-DIFF 2	RTU REAGENT	
Product code:	SP2-RTU	Date of compilation:	14 November 2022	Version: 3

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



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Trading name:		SPERM-DIFF 2	RTU REAGENT		
Product code:	SP2-RTU	Date of compilation:	14 November 2022	Version: 3	

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

SECTIO	ON 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:		SPERM-DIFF 2	RTU REAGENT	
Product code:	SP2-RTU	Date of compilation:	14 November 2022	Version: 3

	city:					
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposur	e 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 – si	ngle exposure (S	TOT SE):			
		ic effects	l	organ		Note
Oral exposure:	No information		No information		_	
Dermal exposure:	No information		No information		-	
Inhalation exposure			No information	on available	-	
-	:		:		1	
Aspiration	hazard:	No inform	nation available			
		1				
Irritation a	nd corrosion:					
iiiitation a	1					NI-+-
IIIIation a	Exposure time	Species	Evaluation	Method		Note
Skin irritation:	Exposure time	Species rabbit	Evaluation -	Method -	_	Note
	•	•			-	Note
Skin irritation:	-	rabbit	-	-		Note
Skin irritation:	- -	rabbit	-	-		Note
Skin irritation: Eye irritation:	- -	rabbit rabbit	-	-		Note
Skin irritation: Eye irritation: Sensitizatio	- -	rabbit rabbit able	-	-		Note
Skin irritation: Eye irritation: Sensitizatio Dermal exposure: Inhalation exposure:	- - on No information avail	able	-	-		NOTE
Skin irritation: Eye irritation: Sensitizatio Dermal exposure: Inhalation exposure:	- - On No information avail No information avail	rabbit rabbit able able I, chemical and t ause irritation of levels of concent g, aspiration cause	oxicological chara mucosa, tingling ration may cause ses coughing, diff	- - - - - - - - - - - - - - - - - - -	- the mout	th, burning ain and vomitin



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Trading name:				SPERM-DIF	F 2 RTU REAGE	ENT	
Product code:	SP	2-RTU	Date o	f compilatio	n: 14 Novemb	oer 2022	Version: 3
Inhalation expos	ure:		large amount: eezing, headae	•	inadequately ver ea.	ntilated perime	ter may cause
Eye exposure:		Direct eye co sensation.	ntact may cau	se slight to m	noderate irritation	, lacrimation a	nd burning
Poposto	d doc	tovicity (sub	acute, subchro	nic chronic)			
Repeate		Dose Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No availa	information able	No information available	No information available	No information available	No informatior available	ı -
Subacute dermal	No availa	information able	No information available	No information available	No information available	No informatior available	ı -
Subacute inhalation	No availa	information able	No information available	No information available	No information available	No informatior available	n -
Subchronic oral	No availa	information able	No information available	No information available	No information available	No informatior available	ı -
Subchronic dermal	No availa	information able	No information available	No information available	No information available	No informatior available	ı -
Subchronic inhalation	No availa	information able	No information available	No information available	No information available	No informatior available	ı -
Chronic oral	No availa	information able	No information available	No information available	No information available	No informatior available	ı -
Chronic dermal	No availa	information able	No information available	No information available	No information available	No informatior available	ı -
Chronic inhalation	No availa	information able	No information available	No information available	No information available	No information available	ı -
Specific	target	organ toxicit	y – repeated e		)T RF):		
opeenie			pecific effects		Target or	gan	Note
Subacute oral			tion available	Ν	lo information ava		-
Subacute dermal		No informa	tion available	Ν	lo information ava	ailable	-
Subacute inhalat	ion	No informa	tion available	N	lo information ava	ailable	_



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Product code:       SP2-RTU       Date of compilation:       14 Novembression         Subchronic oral       No information available       No information available       No information available         Subchronic inhalation       No information available       No information available       No information available         Subchronic oral       No information available       No information available       No information available         Chronic oral       No information available       No information available       No information available         Chronic dermal       No information available       No information available       No information available         Chronic inhalation       No information available       No information available       No information available         Chronic inhalation       No information available       No information available       No information available         Chronic inhalation       No information available       No information available       No information available         CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)       Current studies on test animals did not information available	railable - railable - railable - railable - railable - railable -
Subchronic dermalNo information availableNo information availableSubchronic inhalationNo information availableNo information availableChronic oralNo information availableNo information availableChronic dermalNo information availableNo information availableChronic inhalationNo information availableNo information availableChronic inhalationNo information availableNo information availableCMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	railable - railable - railable - railable - railable -
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         Chronic inhalation       No information available       No information available         CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	railable - railable - railable -
Chronic oral       No information available       No information available         Chronic dermal       No information available       No information available         Chronic inhalation       No information available       No information available         CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	railable - railable -
Chronic dermal       No information available       No information available         Chronic inhalation       No information available       No information available         CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	ailable -
Chronic inhalation       No information available       No information available         CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	ailable -
Carcinogenicity:Current studies on test animals did not inMutagenicity in-vitro:Current in vitro tests did not indicateGenotoxicity:No information availableMutagenicity in-vivo:Current in vivo tests did not indicateGerm cell mutagenicity:No information availableReproductive toxicity:No toxicity on reproductive organs organs.	e mutagenic effects.

SECTION 12. Ecologi	cal informa	tion				
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



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

Trading nam	ie:			SPERM-I	DIFF 2	RT	U REAGEN	т			
Product cod	e:	SP2-RTU		Date of compila	tion:	14	November	· 2022	Vei	rsion:	3
Fish		LC <sub>50</sub>	96 hou	rs No informat available	-	-	nformation able	No informatio available	on	-	
Crustacea:		EC <sub>50</sub>	48 hou	rs No informat available		-	nformation lable	No informatio available	on	-	
Algae/aquatic	: plants	5 IC <sub>50</sub>	72 hou	rs No informat available			nformation lable	No informatio available	on	-	
Other organis		- and degrad	- ability	-	-	-		-		-	
12.2. Persi Abio	stence tic deg De	and degrad radation egradation h	ability alf-lives	Methoc				valuation			Note
12.2. Persi	stence tic deg De	and degrad radation	ability alf-lives				Ev No informa	valuation	ble	-	Note
12.2. Persi Abio Marine	stence tic deg De No ir No ir	and degrad radation egradation h nformation a	ability alf-lives available available	Methoo No information No information	availab availab	ble	No informat	valuation tion availat	ole		Note
12.2. Persi Abio Marine water Fresh water Air	stence tic deg De No ir No ir No ir	and degrad radation egradation h nformation a nformation a	ability alf-lives available available available	Method No information No information No information	availab availab availab	ole ole	No informat No informat No informat	valuation tion availat tion availat tion availat	ole ole	-	Note
12.2. Persi Abio Marine water Fresh water	stence tic deg De No ir No ir No ir	and degrad radation egradation h nformation a	ability alf-lives available available available	Methoo No information No information	availab availab availab	ole ole	No informat	valuation tion availat tion availat tion availat	ole ole	-	Note
12.2. Persi Abio Marine water Fresh water Air Soil	stence tic deg De No ir No ir No ir	and degrad radation egradation h nformation a nformation a nformation a	ability alf-lives available available available	Method No information No information No information	availab availab availab	ole ole	No informat No informat No informat	valuation tion availat tion availat tion availat	ole ole	-	Note
12.2. Persi Abio Marine water Fresh water Air Soil	stence tic deg No ir No ir No ir No ir egrada	and degrad radation egradation h nformation a nformation a nformation a	ability alf-lives available available available available	Method No information No information No information	availab availab availab	ole ole	No informat No informat No informat	valuation tion availat tion availat tion availat	ole ole	-	Note

#### Bioaccumulative potential 12.3.

Value	Concentration	рΗ	°C	Method	Evaluation	Note	
	No information available	-	-	No information available	No information available	-	
Bio	oconcentration factor	(BCF)					
Value	Value Species			Method Evaluation		Note	



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Tradin	g name:		SPERM-DIFF 2 RTU REAGENT									
Produ	ct code:	de: SP2-RTU			ate of c	ompil	ation:	14 No	vember 2	2022	Ve	ersion: 3
		1										
No info availab	ormation le	No availa	inform ble	ation	No info availabl		on	No info availab	ormation le		No info availabl	rmation e
	Chronic	ecotoxici	ty									
	Value		Dose		osure ime	Spe	ecies	Met	hod	Eva	aluation	Note
Chronio	c toxicity o	n fish	LC <sub>50</sub>	No infor availa	mation able	No inforr availa	nation Ible	No inform availab	ation i	No inforr availa	mation able	-
	c toxicity o ea ( <i>Daphn</i>		EC <sub>50</sub>	No information		No inforr availa	mation able	No inform availab	ation i	-	o formation - vailable	
			:	:	i			:	i			
12.4.	Mobility	in soil										
	Known c	r predict	ed distributi	on in e	environm	ental c	compart	ments:				
	No infor	mation a	vailable									
	Surface t	ension:					[					
	Value		°C	Concentration		Metho	od			Note		
	No informat available	-	o formation ailable		No information available		No inf availat	information ilable		-		
		L		<u></u>			<u>.</u>					
	Adsorpti	on / desc	orption						:			
Transpo	ort	A/D coe <sup>.</sup> Henry's c		lc	og Kow	E١	vaporati	on rate	Method			Note
Soil-wa	Soil-water No information No information N					No information _						
Water-	NoinformationNo informationNo informationavailableavailableavailableavailable			nation No information - available								
Soil-air No informa available		nformation	No ir availa	nformatio able		o inform ailable	nation	No information				
	i											
12.5.			d vPvB asses	sment								
	No information available											



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Trading name:	SPERM-DIFF 2 RTU REAGENT						
Product code:	SP2-RTU	Date of compilation:	14 November 2022	Version: 3			

12.6.	Endocrine disrupting propert	ies					
	No known endocrine disrupting properties that affect the environment.						
12.7.	Other adverse effects						
	No adverse effects are expec	ted.					
SECTIO	N 12 Dispession	-					
13.1.	N 13. Disposal consideration Waste treatment methods	IS					
13.1.	Waste treatment methods						
13.1.1.	.1. Product/Packaging disposal:						
	Submit for disposal to the I Protection.	egal person authorized by the Ministry of Environmental and Nature					
13.1.2.	Waste codes/waste designa	ations according to Law:					
	No information available						
13.1.3.	Waste treatment – relevant	information:					
	No information available						
	:						
13.1.4.	Sewage disposal – relevant	information:					
	Waste must not be dispose	ed of into the sewage system.					
	i.						
13.1.5.	Other disposal recommend						
	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 provis	sions:					
	-						
SECTIO	N 14. Transport information						
	Transporting/shipment by ro						
UN num		Not subject to transport regulations.					
	per shipping name:	-					
Transpo	ort hazard class(es):	-					



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Trading name:		SPERM-DIFF 2 RTU REAGENT						
Product code:	SP2-RTU	Date of compilation:	14 November 2022	Version:	3			
		T	-					
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	s for user:	-						
Transporti	ng/shipment by rail (R	ID)						
UN number:		Not subject to transport	regulations.					
UN proper shipping	g name:	_						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	s for user:	-						
Inland wat	erway transport (ADN	)						
UN number:		Not subject to transport	regulations.					
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	s for user:	-						
Transporti	ng/shipment by sea (l	MDG)						
UN number:		Not subject to transport	regulations.					
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	for user:	-						
Transporti	ng/shipment by air (IC	AO-TI/IATA-DGR)						
UN number:		Not subject to transport regulations.						
UN proper shipping name:		-						
Transport hazard class(es):		-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	s for user:	-						
Further information	The product is	not subject to classificatio	n					



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Trading name:		RTU REAGENT		
Product code:	SP2-RTU	Date of compilation:	14 November 2022	Version: 3

	EU regulations					
	Authorization and/or rest	trictions of use				
	Authorizations:	-				
	Restrictions:	-				
	Other EU regulations:	<ul> <li>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</li> <li>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</li> <li>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</li> <li>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</li> <li>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</li> </ul>				
	Information according 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 an on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act				
5.2.	Chemical safety assessme					

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



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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.	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:	SPERM-DIFF 3 RTU REAGENT					
Product code:	SP3-RTU	Date of compilation:	14 November 2022	Version: 4		

SECTI	ON 1: Identification of t	he substan	ce/mixture	and of the company/undertaking		
1.1.	Product identifier					
	Trading name:	SPERM-D	SPERM-DIFF 3 RTU REAGENT			
	Chemical name:	-	-			
	Catalogue number:	SP3-RTU				
1.2.	Relevant identified use	s of the sub	stance or mi	xture and uses advised against		
	Uses:		Blue com	ponent of Sperm-Diff RTU kit.		
	Uses advised against:		Only the i	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 safet	y data sheet			
	Supplier:	BioGnost Ltd.				
	Address:		Medjugorska 59, Zagreb			
	Telephone number:	-	+385 1 2409997			
	Fax no.:	-	+385 1 2404039			
	e-mail of competent p	erson: <u>I</u>	msds@biognost.hr			
	National contact:	-	-			
1.4.	Emergency telephone	number				
	National Protection an	d Rescue Di	irectorate:	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 subst	ance.	-	
2.1.2.	Additional information			
*For full text of Hazard- and EU Hazard-statements: see Section 16				
2.2.	Label elements			
	Product identification:	SPERM-DIFF	3 RTU REAGENT	
	Identification number:	-		
	Authorization no.:	-		
	Hazard pictograms:	-		



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

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

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



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Tradin	ng name:	SPERM-DIFF 3 RTU REAGENT		
Produ	uct code: SP3-RTU Date of co		Date of compilation: 14 November 2022 Version: 4	
	Following ingestion:burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes		abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause	
4.3.	Indicatio	n of any immediate medical attention and special treatment needed		
	-			

SECTIO	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 environmer			

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



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			Where possible, the substar material (sand, diatomaceou in tightly closed impermeab	us earth, vermiculite). Plac	0

		persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.	
6.3.3.	Other information:	-	
6.4.	Reference to other sections		
	See Section 7 for information about secure handling.		
	See Section 8 for information about personal protective equipment.		
	See Section 13 for information about containment.		

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



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	1	:	:	1 1

Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposur	e contro	ols/persona	al protec	tion					
8.1. Control para	meters								
Substance					exposure limit term values	Biological limit values			
					ppm	mg/m <sup>3</sup>			
-		-			-	-	No inform	ation available	
Substance - name:									
EC No: -		CAS No:	-						
DNEL									
				Ind	lustrial				
Route of exposure:	ŀ	Acute		Acute	e	Chron	ic	Chronic	
Route of exposure.	effe	ect local	effect sys		temic	effect lo	ocal	effect systemic	
Oral -			-			-			
Inhalation -			-			-	-		
Dermal	Dermal -		-			-	-		
Critical physical parar	neters: s	olubility, fla	mmabilit	ty, cor	rosivity:	-			
			1	Cor	nsumer				
Route of exposure:	A	Acute		Acute	е	Chron	ic	Chronic	
Route of exposure.	effe	ect local	effe	ect syst	temic	effect lo	ocal	effect systemic	
Oral	-		-			-			
Inhalation	-		-			-			
Dermal	-		-			-	·		
PNEC									
Environmental protect	tion tar	get			PNEC				
Fresh water					No information available				
Freshwater sediments	5				No information available				
Marine water					No information available				
Marine sediments					No infor	mation availabl	e		
Food chain					No infor	mation availabl	е		
Microorganisms in se	wage tr	eatment			No infor	mation availabl	e		
Soil (agricultural)					No infor	mation availabl	e		



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Air			ļ	No information available				
8.2.	Exposure controls							
8.2.1.	Appropriate engineering	controls	1					
	Substance/mixture relate measures to prevent exp during identified uses:		•	roduct in well ventilated rooms. Use personal protective nt. Do not eat, drink or smoke in the workspace.				
	Structural measures to pr exposure:	revent	No inform	nation available				
	Organisational measures prevent exposure:	to	-	tion of work in order to reduce other worker's influence ork process.				
	Technical measures to pr exposure:	event		oper workspace ventilation in order to keep ation levels in air below permitted levels.				
8.2.2.	Personal protection equi	pment						
8.2.2.1.	Eye and face protection:		Safety glasses that stick to face (preventing splashing) (EN 166) or visor.					
8.2.2.2.	Skin protection	Skin protection						
8.2.2.2.	Hand protection:		ord EN 374. Glove ma Glove thi	must be according to the EU Directive 2016/425/EEC and terial: nitrile rubber ckness: $\geq$ 0.50 mm				
			Break thr	ough time: >480 min				
	Other skin protection:		ar antistatic clothing made of natural fibers (such as cotton) with long ves (EN 13034), and shoes that cover the entire foot (EN 10335).					
8.2.2.3.	Respiratory protection:	filter f	or organic v	e mask (EN 136) or half mask (EN 140) equipped with a vapors, type "A" (boiling point >65°C) acording to EN n concentration levels exceed GVI.				
8.2.2.4.	Thermal hazards:	No inf	ormation a	vailable				
8.2.3.	Environmental exposure	controls						
	Substance/mixture relate measures to prevent exp		See Section 6					
	Structural measures to pr exposure:	revent	Use mode	ern equipment.				
	Organisational measures prevent exposure:	to	Adapt the workplace	e work process to the required working conditions of the e.				
	Technical measures to pr exposure:	event	See Section	on 6				



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Color:blueNo information availableOdour/odour threshold:no odor/no information availableNo information availableMelting point / freezing point:No information availableNo information availableBoiling point or initial boiling point and boiling range:No information availableNo information availableFlammability:No information availableNo information availableNo information availableLower and upper explosion limit:No information availableNo information availableFlash point:No information availableNo information availableAuto-ignition temperature:No information availableNo information availableDecomposition temperature:No information availableNo information availablepH:6.3 – 7.3No information availableSolubility:No information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableVapour pressure:No information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information availableNo information available			Value	Method
Odour/odour threshold:no odor/no information availableNo information availableMelting point / freezing point:No information availableNo information availableBoiling point or initial boiling point and boiling range:No information availableNo information availableFlammability:No information availableNo information availableNo information availableLower and upper explosion limit:No information availableNo information availableFlash point:No information availableNo information availableAuto-ignition temperature:No information availableNo information availableDecomposition temperature:No information availableNo information availablepH:6.3 – 7.3No information availableNo information availableSolubility:No information availableNo information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableVapour pressure:No information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information availableNo information available	Physica	l state:	liquid	No information available
Odour/odour threshold:availableNo information availableMelting point / freezing point:No information availableNo information availableBoiling point or initial boiling point and boiling range:No information availableNo information availableFlammability:No information availableNo information availableNo information availableLower and upper explosion limit:No information availableNo information availableNo information availableFlash point:No information availableNo information availableNo information availableNo information availableDecomposition temperature:No information availableNo information availableNo information availableNo information availablepH:6.3 – 7.3No information availableNo information availableNo information availableNo information availableSolubility:No information availableNo information availableNo information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableNo information availableVapour pressure:No information availableNo information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information availableNo information available	Color:		blue	No information available
Boiling point or initial boiling point and boiling range:No information availableNo informatFlammability:No information availableNo informatLower and upper explosion limit:No information availableNo informatFlash point:No information availableNo informatAuto-ignition temperature:No information availableNo informatDecomposition temperature:No information availableNo informatpH: $6.3 - 7.3$ No informatKinematic viscosity:No information availableNo informatSolubility:No information availableNo informatPartition coefficient n-octanol/water (log value):No information availableNo informatVapour pressure:No information availableNo informatDensity and/or relative densityNo information availableNo informat	Odour/	odour threshold:	· ·	No information available
and boiling range:No information availableNo informationFlammability:No information availableNo informationLower and upper explosion limit:No information availableNo informationFlash point:No information availableNo informationAuto-ignition temperature:No information availableNo informationDecomposition temperature:No information availableNo informationpH: $6.3 - 7.3$ No informationKinematic viscosity:No information availableNo informationSolubility:No information availableNo informationPartition coefficient n-octanol/water (log value):No information availableNo informationVapour pressure:No information availableNo informationDensity and/or relative densityNo information availableNo information	Melting	point / freezing point:	No information available	No information available
Lower and upper explosion limit:No information availableNo information availableFlash point:No information availableNo information availableAuto-ignition temperature:No information availableNo information availableDecomposition temperature:No information availableNo information availablepH: $6.3 - 7.3$ No information availableKinematic viscosity:No information availableNo information availableSolubility:No information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableVapour pressure:No information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information availableNo information available			No information available	No information available
Flash point:No information availableNo information availableAuto-ignition temperature:No information availableNo information availableDecomposition temperature:No information availableNo information availablepH: $6.3 - 7.3$ No information availableKinematic viscosity:No information availableNo information availableSolubility:No information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableVapour pressure:No information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information availableNo information available	Flamma	ability:	No information available	No information available
Auto-ignition temperature:No information availableNo information availableDecomposition temperature:No information availableNo information availablepH: $6.3 - 7.3$ No information availableNo information availableKinematic viscosity:No information availableNo information availableNo information availableSolubility:No information availableNo information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableVapour pressure:No information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information availableNo information available	Lower a	and upper explosion limit:	No information available	No information available
Decomposition temperature:No information availableNo information availablepH: $6.3 - 7.3$ No information availableNo information availableKinematic viscosity:No information availableNo information availableNo information availableSolubility:No information availableNo information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableVapour pressure:No information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information availableNo information available	Flash p	oint:	No information available	No information available
pH:6.3 – 7.3No informationKinematic viscosity:No information availableNo informationSolubility:No information availableNo informationPartition coefficient n-octanol/water (log value):No information availableNo informationVapour pressure:No information availableNo informationDensity and/or relative densityNo information availableNo information	Auto-ig	nition temperature:	No information available	No information available
Kinematic viscosity:No information availableNo information availableSolubility:No information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableVapour pressure:No information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information availableNo information available	Decom	position temperature:	No information available	No information available
Solubility:No information availableNo information availablePartition coefficient n-octanol/water (log value):No information availableNo information availableVapour pressure:No information availableNo information availableNo information availableDensity and/or relative densityNo information availableNo information available	pH:		6.3 – 7.3	No information available
Partition coefficient n-octanol/water (log value):No information availableNo informatVapour pressure:No information availableNo informatDensity and/or relative densityNo information availableNo informat	Kinema	tic viscosity:	No information available	No information available
(log value):No information availableNo informationVapour pressure:No information availableNo information availableDensity and/or relative densityNo information availableNo information available	Solubili	ty:	No information available	No information available
Density and/or relative density     No information available     No information available			No information available	No information available
	Vapour	pressure:	No information available	No information available
Relative vapour density: No information available No informa	Density	and/or relative density	No information available	No information available
	Relative	e vapour density:	No information available	No information available
Particle characteristics: No information available No informa	Particle	characteristics:	No information available	No information available

SECTIO	ON 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:		SPERM-DIFF 3	RTU REAGENT	
Product code:	SP3-RTU	Date of compilation:	14 November 2022	Version: 4

	city:					
Route of exposure:	Method	Species Effective D Species LD <sub>50</sub> /LC <sub>50</sub> ATE <sub>mixtur</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 – si	ngle exposure (	STOT SE):			
	Specif	ic effects	Target	organ		Note
Oral exposure:	No information	available	No information	on available	-	
Dermal exposure:	No information	available	No information	No information available		
Inhalation exposure	: No information	available	No information	on available	-	
Aspiration	hazard:	No info	rmation available			
Irritation a	nd corrosion:					
	Exposuro timo	Species	Evaluation	Method		Note
	Exposure time					
Skin irritation:	-	rabbit	-			
Skin irritation: Eye irritation:	•	•	-			
	-	rabbit				
	-	rabbit				
Eye irritation:	-	rabbit rabbit				
Eye irritation: Sensitizatio	- -	rabbit rabbit able				
Eye irritation: Sensitizatio Dermal exposure: Inhalation exposure:	- - on No information avail	able	-			
Eye irritation: Sensitizatio Dermal exposure: Inhalation exposure:	- - No information avail No information avail related to the physica Swallowing may c sensation; higher	rabbit rabbit able able I, chemical and ause irritation o levels of concer g, aspiration ca	- toxicological chara of mucosa, tingling ntration may cause uses coughing, diff		minal pa	ain and vomiting



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Trading name:		SPERM-DIFF 3 RTU REAGENT							
Product code:	SP	3-RTU	Date o	f compilatio	n: 14	Novemb	er 2022	Version:	4
Inhalation exposi	lire <sup>.</sup>		large amount: eezing, headad	•	•	uately vent	tilated perime	eter may cau	ise
Eye exposure:		Direct eye co sensation.	ntact may cau	se slight to m	noderate	e irritation,	lacrimation a	nd burning	
Repeate	ad dose	tovicity (sub	acute, subchro	nic chronic)					
Repeate		Dose	Exposure time	Species	Me	thod	Evaluation	Note	
Subacute oral	No availa	information able	No information available	No information available		ormation ilable	No informatio available	n -	
Subacute dermal	No availa	information able	No information available	No information available		ormation ilable	No informatio available	n -	
Subacute inhalation	No availa	information able	No No information informati available available			ormation ilable	No informatio available	n -	
Subchronic oral	No availa	information able	No No information informati available available			ormation ilable	No informatio available	n -	
Subchronic dermal	No availa	information able	No No information informati available available			ormation ilable	No informatio available	n -	
Subchronic inhalation	No availa	information able	No information available	No information available		ormation ilable	No informatio available	n -	
Chronic oral	No availa	information able	No information available	No information available		ormation ilable	No informatio available	n -	
Chronic dermal	No availa	information able	No information available	No information available		ormation ilable	No informatio available	n -	
Chronic inhalation	No availa	information able	No information available	formation information		ormation ilable	No informatio available	n -	
Specific	target	organ toxicit	y – repeated e	xposure (STO	T RE):				
•		<u> </u>	pecific effects	<u> </u>	-	Target org	an	Not	e
Subacute oral		No informa	tion available	N	lo inforn	nation ava	ilable	-	
Subacute dermal		No informa	tion available	N	lo inforn	nation ava	ilable	-	
Subacute inhalat	ion	No informa	tion available	N	lo inforn	nation ava	ilable	-	



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Trading name:		SPERM-DIFF 3 RTU REAGENT									
Product code:	SP3-	RTU	Date of com	Date of compilation: 14 November 2022 Versio							
Subchronic oral		No informat	ion available	available No information available							
Subchronic derm	al	No informat	ion available	No information available	-						
Subchronic inhala	ation	No informat	ion available	No information available	-						
Chronic oral No informatio		ion available	No information available	-							
Chronic dermal No informat		ion available	No information available	-							
Chronic inhalatio	n	No informat	ion available	No information available	-						
CMR effects (carcinogenicity; r         Carcinogenicity:         Mutagenicity in-vitro:         Genotoxicity:         Mutagenicity in-vivo:         Germ cell mutagenicity:         Reproductive toxicity:		Current <i>in viti</i> No information Current <i>in viv</i> No information	Current studies on test animals did not indicate carcinogenic Current <i>in vitro</i> tests did not indicate mutagenic effects. No information available Current <i>in vivo</i> tests did not indicate mutagenic effects. No information available No toxicity on reproductive organs was determined in								
11.2. Informat 11.2.1. Endocrir	ion on c ne disrup	other hazard oting proper	ties:	-							
			ing properties that	affect human health.							
11.2.2. Other in	formatio	on:									
-											

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				



#### SAFETY DATA SHEET **BIOGNOST**<sup>®</sup> According to Regulation (EC) No. 1907/2006 n (FU) No 2020/879 dad by Pa aulatio

Tradin	g name:		SPERM-DIFF 3 RTU REAGENT									
Product code:		SF	93-RTU		Date of compilation:		1	4 November	r 2022	Versior	n: 4	
Fish			LC <sub>50</sub>	96 hou	ırs	No information available	_	information ilable	No informatic available	on -		
Crustacea:			EC <sub>50</sub>	48 hou	ırs	No information available		information ilable	No informatic available	on -		
Algae/a	aquatic plar	nts	IC <sub>50</sub>	72 hou	ırs	No information available		information ilable	No informatic available	on -		
Other o	Other organisms					-	-					
12.2.	Persistend	e an	id degrad	ability								
	Abiotic de	egrad	dation									
		Degr	adation h	alf-lives		Method		Evaluation			Note	
Marine water	Nc	infc	ormation a	available	N	No information availa		able No information availa		le	-	
Fresh w	vater No	o info	ormation a	available	No	No information availa		le No information available		le	-	
Air No information available		available	N	No information availa		le No information available		le	-			
Soil	Nc	info	ormation a	available	No	o information availa	able	No informa	tion availab	le	-	

% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available
12.3. Bioaccumulative potential				

Oc	tanol-water partition	coefficier	nt (log Ko	ow)		
Value	Concentration	pН	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-
Bio	oconcentration factor	(BCF)	:			:
Value	e Spec	ies		Method	Evaluation	Note



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Tradin	g name:		SPERM-DIFF 3 RTU REAGENT										
Produ	ct code:	SP3-I	RTU	D	ate of c	ompil	ation:	14 No	vember 2	022		Version:	4
No info availab	ormation le	No availa	inform ble	nation No informa available			n	No info availab	formation ble		No information available		n
	Chronic e	ecotovici	tv										
	Value		Dose		osure ime	Spe	ecies	Met	hod	Eva	aluatic	on	Note
Chronie	c toxicity o	n fish	LC <sub>50</sub>	No infor availa	mation able	No inforr availa	mation able	No informa availab	ation i	No nforr availa	matior able	n -	
	c toxicity o ea ( <i>Daphn</i>		EC <sub>50</sub>	No infor availa	mation able	No infori availa	mation able	No informa availab	ation i	-			
12.4.	Mobility Known o No infor Surface t	r predict mation a	ed distributi vailable	on in e	environm	ental c	compart	ments:					
	Value		°C	C	oncentra	tion		Metho	d			Note	
	No informat available	on in		No	informat ilable		No inf availat	ormation	mation _				
	Adsorpti	on / desc	orption										
Transpo	ort	A/D coe Henry's c	fficient	lo	og Kow	E١	vaporati	on rate	Met	hod		No	ote
Soil-wa	Soil-water No information		No ir availa	nformatio able				No information		-			
Water-	air No avai	NoinformationNo informationNo infoavailableavailableavailableavailable		o inform ailable	nation No information		-						
Soil-air	Soil-air No information available		No ir availa	nformatio able		o inform ailable	nation No informati available			on	-		
12.5.			d vPvB asses	sment									
	No information available												



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Trading name:	SPERM-DIFF 3 RTU REAGENT				
Product code:	SP3-RTU	Date of compilation:	14 November 2022	Version: 4	

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



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Trading name:	SPERM-DIFF 3 RTU REAGENT					
Product code:	SP3-RTU	Date of compilation: 14 November 2022	Version: 4			
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Transporti	ng/shipment by r	ail (RID)				
UN number:		Not subject to transport regulations.				
UN proper shipping	g name:	-				
Transport hazard cl	ass(es):	-				
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Inland wat	erway transport ( <i>i</i>	ADN)				
UN number:		Not subject to transport regulations.				
UN proper shipping	g name:	-				
Transport hazard cl	ass(es):	-				
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Transporti	ng/shipment by s	ea (IMDG)				
UN number:		Not subject to transport regulations.				
UN proper shipping	g name:	-				
Transport hazard cl	ass(es):	-				
Packing group:		-				
Environmentally ha	zardous:	-				
Special precautions	for user:	-				
Transporti	ng/shipment by a	ir (ICAO-TI/IATA-DGR)				
UN number:		Not subject to transport regulations.				
UN proper shipping name:		-				
Transport hazard class(es):		-				
Packing group:		-				
Environmentally hazardous:		-				
Special precautions	for user:	-				
Further information	n: The produ	ict is not subject to classification.				



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Trading name:	SPERM-DIFF 3 RTU REAGENT				
Product code:	SP3-RTU	Date of compilation:	14 November 2022	Version:	4

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

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



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Trading name:	SPERM-DIFF 3 RTU REAGENT				
Product code:	SP3-RTU	Date of compilation:	14 November 2022	Version: 4	

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classifi	cation	Classification procedure	
-		-	
16.5.	5.5. 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