

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

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 component of Sperm-Diff RTU kit.		
	Uses advised against:	Only the iden	tified uses are advised.	
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3.	Details of the supplier of the safety data sheet			
	Supplier:	BioGnost Ltd.		
	Address:	Medjugorska 59, Zagreb		
	Telephone number:	+385 1 2409997		
	Telefax:	+385 1 2404039		
	e-mail of competent person:	msds@biognost.hr		
	National contact:			
1.4.	Emergency telephone numbers			
	National Protection and Rescue Directorate:		112	
	Medical information:		+385 1 2348 342	
	Other information:		-	

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



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	Product identification:	SPERM-DIFF 1 RTU REAGENT	
	Identification number:	-	
	Authorisation number:	-	
	Hazard pictograms:	GHS02 GHS06 GHS08	
	Signal word:	Danger	
	Hazard statements:	H225 Highly flammable liquid and vapor. H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled. H370 Causes damage to organs (eyes).	
	Precautionary statements:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves, protective clothing, eye protection, face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.	
	Supplemetal hazard		
	information (EU):	-	
2.3.	Other hazards		
	Endocrine Disrupting Properties: No known endocrine disrupting properties Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.		



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SECTION 3. 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 measures		
	General notes:	First aider needs to protect himself.	
	Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration, if necessary also oxygen. In case of irregular breathing or respiratory arrest provide artificial respiration.	
	Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.	
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.	
	Following ingestion:	Rinse with water and expectorate. Make the afflicted person drink one glass (100 ml) of 40% ethanol (adult dose). Call a doctor immediately (mention methanol ingestion). Only in exceptional cases, if no medical care is available within one hour, induce vomiting (only in fully conscious persons) and make victim drink ethanol again (approx. 0.3 ml of a 40% alcoholic beverage/kg body weight/hour). Do not attempt to neutralise.	
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.	
4.2.	Most important symptoms and effects, both acute and delayed		
	Following inhalation:	Irritation to the airways and possible damage to the lung probably only through very high vapor concentrations, then even absorptive-toxic effects.	
	Following skin contact:	Minor/no irritation, degreasing action, following massive contact watch for danger of skin absorption and possibly delayed onset of systemic effects.	
	Following eye contact:	Slight through to moderate irritation due to the liquid and concentrated vapors conjunctivitis, later chemosis, apparently minor probability of cornea damage, later occurring visual disturbances are caused not primarily through local contact but are systemically related (following absorption).	
	Following ingestion:	Stomach and bowel irritation, feeling unwell, nausea, vomiting, strong abdominal pain. Absorption may cause toxic effects.	



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

SECTI	SECTION 5. Firefighting measures			
5.1.	Extinguishing media			
	Suitable extinguishing media:	water spray, foam, dry powder, CO ₂		
	Unsuitable extinguishing media:	No information available		
5.2.	Special hazards arising from the sul	bstance or mixture		
	Hazardous by products of fire:	Combustible. Vapours are heavier than air and may spread along floors. Forms explosive mixtures with air at ambient temperatures. Development of hazardous combustion gases or vapours possible in the event of fire.		
5.3.	Advice for firefighters			
	Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.			
5.4.	Additional information	Additional information		
	Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.			

SECTIO	ECTION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment:		Use personal protective equipment (see Section 8).		
	Accident prevention m	ethods:	Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.s		
	Emergency procedures: Mark the area using proper signs.		Mark the area using proper signs.		
6.1.2.	For emergency responders:				
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).				
6.2.	Environmental precaut	ions:			
	Do not let product enter drains. Risk of explosion.				
6.3.	Methods and materials for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Cover drains. Collect, bind and pump off spills.			



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

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



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		Do no	t place the unused mater	ial in the storage room		

	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposure	e contr	ols/persona	l protec	tion			
8.1. Control para	meters						
Substance CAS N		Occupational e				ological limit values	
				ppm	mg/m³		
Methanol		67-56	-1	200	260	(7.0 mg/	nol/mol of creatinine* 'g of creatinine*), shift urinary excretion
* For all results pertai consideration	ning cre	atinine level	s, creatir	nine concentration	on < 0.5 g/l and	d > 3.0 g/	I may not be taken into
Substance: -							
EC No: -		CAS No:	-				
DNEL							
Industrial							
Route of	Acute		Acute		Chron	ic	Chronic
exposure:	effe	ect local	effe	fect systemic effect lo		ocal	effect systemic
Oral	-		-		-		-
Inhalation	260 mg (metha		_	260 mg/m³ 260 mg/m³ (methanol)			260 mg/m³ (methanol)
Dermal	-		40 mg/	kg (methanol)			40 mg/kg (methanol)
Critical physical paran	neters: s	olubility, fla	mmabilit	ty, corrosivity:		-	
				Consumer	·		
Route of exposure:		Acute ect local	effe	Acute ect systemic	Chron effect lo		Chronic effect systemic
Oral	-		8 mg/k	g (methanol)	-		8 mg/kg (methanol)
Inhalation	50 mg, (metha		50 mg/ (metha		50 mg/m ³ (methanol)		50 mg/m³ (methanol)
Dermal	-		8 mg/k	g (methanol)			8 mg/kg (methanol)
PNEC							



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protection target	PNEC
	154 mg/l (methanol)
liments	570.4 mg/kg (methanol)
	15.4 mg/l (methanol)
nts	No information available
	No information available
ns in sewage treatment	100 mg/l (methanol)
al)	23.5 mg/kg (methanol)
	No information available
posure controls	
ppropriate engineering measures	
ubstance/mixture related easures to prevent exposure uring identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
ructural measures to prevent posure:	No information available
rganisational measures to prevent posure:	Organization of work in order to reduce other worker's influence during work process.
echnical measures to prevent sposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
ersonal protection equipment	
re 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).
in protection:	
and protection:	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 Glove thickness: 0.70 mm Break through time: > 480 min Splash contact: Gloves material: viton (R) Glove thickness: 0.70 mm
and pro	otection:



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

9.1.	Information on basic physical and	chemical properties	
		Value	Method
	Physical state:	liquid	No information available
	Colour:	light blue	No information available
	Odour/odour threshold:	methanol like/no information available	No information available
	Melting point / freezing point:	-98 °C	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
	Lover 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



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

SECTIO	ON 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).
10.3.	Possibility of hazardous reactions:	Risk of explosion with: Oxidizing agents, alkali metals, nitric acid, sulphuric acid, hydrogen peroxide, permanganic acid, sodium hypochlorite. 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, Raneynickel/hydrogenation, acid anhydrides, acid halogenides, tetrachloromethane/light metals.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Various plastics, magnesium, zinc alloys, aluminium and galvanised iron.
10.6.	Hazardous decomposition products:	No information available.

SECTIO	SECTION 11. Toxicological information								
11.1.	Informat	Information on hazard classes as defined in Regulation (EC) No 1272/2008							
	Acute toxicity:								
Route of exposure:		Method	Species LD ₅₀ /LC ₅₀ at ATE _{mixture}		Exposure time	Results			
Oral:		No information available	rat	LD ₅₀	-	125.13 mg/kg (methanol)			
Dermal:		No information available	rabbit	LD ₅₀	-	375.13 mg/kg (methanol)			



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Product code:	SP1-RTU	Date of com	te of compilation: 14 November 2022 Version: 3					
Inhalation:	No information available	rat	LC ₅₀	4 h	3.88 mg/l (methanol)			
Specific	target organ toxicity -	single exposure	(STOT-SF):					
эрсеше	Specific			et organ	Note			
Oral:	No information avail		No information	_	-			
Dermal:	No information avail	lable	No information	on available	-			
Inhalation:	No information avail	lable	Eyes		mixture causes damage to organs			
Aspiration	on hazard:	No inf	ormation available					
1								
Irritation	and corrosion	Specie	- Evaluation	Method	Note			
Skin corrosion/irritation	Exposure tim	ne Specie	es Evaluation -	-	Note drying-out effect resulting in rough and chapped skin			
Serious eye damage/irritation	- 1	_	-	_	irritations of mucous membranes			
Sensitiza	ation							
Skin sensitization		sensitization.						
Respiratory sensitization:	No information							
Cumpto	ms related to the physi	ical chamical an	d tovical agical sha	ractoristics				
Oral exposure:		irritation, acidos	is, drop in blood p	ressure, feeling	g unwell, vomiting, strong kidnev, cardiac.			
Dermal exposure:	-	itation, defatting	ı; prolonged expos		absorption and greater			
Inhalation exposure:	Airways irritation and dizziness, drowsiness			•				
Eye exposure:		dness, irreversibl	-		s, lesser possibility of /isual impairments may			
Repeate	ed dose toxicity (subact							
	Dose Ex	xposure time	Species	Method	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	Specific effects Target organ	
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	_

Specific target organ toxicity - repeated exposure (STOT-RE):



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

SECTIO	ON 12.	Ecological	information

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



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Crustacea:		EC ₅₀	48 hours		o information vailable	No infor	mation able	No information available		on -	
Algae/aquatic plants:		IC ₅₀	72 hour	rc	o information vailable	No infor availa	mation able	No information - available			
Other organis	ms	-	_	-		-		-		-	
12.2. Persis	stance	e and degrada	ability								
		gradation	ibility								
710101		Degradation h	alf-lives		Method			Evalu	ation		Note
Marine water	<u> </u>	information a			o information ava	ilable	No ir	nformatio		ilable	_
Fresh water	No	information a	vailable	N	o information ava	ilable	No ir	nformatio	n ava	ilable	-
Air	No	information a	vailable	N	o information ava	ilable	No information availa			ilable	-
Soil	No	information a	vailable	N	o information ava	ilable	No ir	nformatio	n ava	ilable	-
-											
Biode	egrad	ation		1				1			
% Degradati	on	Time (da	ays)		Method Evaluation		Evaluatio	n		No	te
-		_		-	No in availa		information - ailable -		-		
12.3. Bioac	cumu	ulative potenti	al								
		ater partition		ent (log	Kow)						
Value	Cor	ncentration	рН	°C	Method		Evalua	ation		N	ote
_	No availa	information able	-	-	-		o inform vailable	nation	-		
Bioco	ncen	tration Factor	(BCF)								
Value		Spec			Method		Evaluation	on		No	ote
No information		No informati available			No information available		No information available		No information available		tion



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	Chronic	ecotoxicity	/								
	Value		Dose	Exposure time		Species	Me	thod	Eval	uation	Note
Chronic toxicity on fish LC ₅		LC ₅₀	No information available		o Iformation vailable	No inform availal	mation No information available			-	
Chronic toxicity on crustacea (Daphnia)		EC ₅₀	No information available		o Iformation vailable	No inform availal		No infor		-	
12.4.	Mobility	in soil									
	Known c	or predicte	d distributi	on in enviro	nmen	tal compartr	ments:				
	No infor	mation av	ailable								
	Surface t	tension:									
	Va	lue	c	'C		Concentrati	oncentration Metho		d N	Note	
	No information No available available		No ir available	information No information		nformation a	available No informat		formation	tion available	
	Adsorpti	ion / desoi	rption			1	i				
Transpo	ort	A/D coeff Henry's co		log Kov	W	Evaporatio	on rate	M	ethod	No	ote
Soil-Wa	nter No	in [.] ilable	formation	No informavailable	ation	No informavailable	ation	No info availabl	rmation e	-	
Water-	Air No ava	in [.] ilable	formation	No informavailable	ation	No informavailable	ation	No info availabl	rmation e	-	
Soil-Air	. No ava	in ilable	formation	No informavailable	ation	No informavailable	ation	No info availabl	rmation e	-	
12.5.	Results o	of PBT and	vPvB asses	ssment							
	Substan	ce(s) in the	mixture d	o(es) not me	et the	criteria for	PBT or vl	PvB			
12.6.	Endocrin	ne disrupti	ng propert	es							
	accordin	g to REAC	H Article 5	not contain o 7(f) or Comr evels of 0.19	nissio:	n Delegated					•



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12.7.	Other adverse effects
	No adverse effects are expected.
SECTIO	N 13. Disposal considerations
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	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.	Waste codes/waste designations according to Low:
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.4.	Sewage disposal – relevant information:
13.1.4.	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.

Transporting/shipment by	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	D)
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland	waterways (ADN)
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IN	/IDG)
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 (ICA	AO-TI/IATA-DGR)
UN number:	1230
UN proper shipping name:	Methanol
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Further information: -	

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



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

	Authorisations and/or res	trictions on use
	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation an Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EC) 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 an 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 Apr 2004 on the limitation of emissions of volatile organic compounds due to the use organic solvents in certain paints and varnishes and vehicle refinishing products an amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safet of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 1 December 2008 on classification, labelling and packaging of substances an mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, an amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
5.2.	Chemical safety assessme	ent
	None	

SECTION 16. Other information				
16.1. Indication of changes:	-			



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

16.2. Abbreviations and acronyms:			ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:		-
16.4. Classification and procedure 1272/2008 (CLP)		the state of the s	used to derive the classification for mixture according to Regulation (EC)
Classifi	cation	1	Classification procedure
_			-
16.5.	Rele	evant H statements (num	per 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.	Training advice:		
16.7.	7. Further information:		** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment
-



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Trading name:	SPERM-DIFF 2		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	nd of the company/undertaking	
1.1.	Product identifier				
	Trading name:	SPERM-DIF	F 2 RTU REA	GENT	
	Chemical name:	-			
	Catalogue number:	SP2-RTU			
1.2.	Relevant identified us	es of the subs	tance or mix	cture and uses advised against	
	Uses:		Red comp	onent of Sperm-Diff RTU kit.	
	Uses advised against:		Only the id	dentified uses are advised.	
	Reason why uses advi			ct is intended for use only as an <i>in vitro</i> diagnostic evice, registered at the Agency for Medicinal Products and evices and there is no reason to use it for other purposes	
1.3.	Details of the supplier	of the safety	data sheet		
	Supplier:	Bi	ioGnost Ltd.		
	Address:	N	ledjugorska	59, Zagreb	
	Telephone number:	+	+385 1 2409997		
	Fax no.:	+	+385 1 2404039		
	e-mail of competent	person: <u>m</u>	msds@biognost.hr		
	National contact:	-	-		
1.4.	Emergency telephone	number			
	National Protection a	nd Rescue Dir	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards identification			
2.1.	Classification of the substance or mixture			
2.1.1.	Classification according to Regula	ation (EC) No 127	2/2008 (CLP)	
	Hazard class and category	/ code:		Hazard statements*:
	Not identified as hazardous subst	ance.	-	
2.1.2.	Additional information			
	-			
*For ful	l text of Hazard- and EU Hazard-sta	atements: see Sec	ction 16	
2.2.	Label elements			
	Product identification:	SPERM-DIFF 2	RTU REAGENT	
	Identification number:	-		
	Authorization no.:	-		
	Hazard pictograms:	-		



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SPERM-DIFF 2 RTU REAGENT				
P2-RTU	Date of compilation:	14 November 2022	Version: 3	
F	P2-RTU			

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

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	-

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



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

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

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

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



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Trading name:	SPERM-DIFF 2 RTU REAGENT					
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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.			
6.3.3.	Other information:	-			
6.4.	Reference to other 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 not sr	away from sources of heat and ignition. Do noke.		
	Measures to prevent aerosol and dust generati	n: Secur	e proper ventilation.		
	Measures to protect the environment:	Preve water	nt spilling into the sewage system and ways.		
	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 ventilated storage rooms, and away from sources of sunlight, and other incompatible substances.			
	Packaging materials:	Manufactu	rer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away tightly clos	from food and drink. Keep the containers sed.		
	Advices for storage equipment:	ventilation. Do not place the unused material in the storage room			
	Further information on storage conditions:				
7.3.	Specific end use(s)				



Microorganisms in sewage treatment

Soil (agricultural)

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

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Trading name:				SPE	RM-DIFF	2 RTU F	REAG	ENT	
Product code:	SP2-RT	U	Date	of cor	mpilation	: 14 N	ovem	ber 2022	Version: 3
Recomme Industrial		cific solutio	ns:		-				
SECTION 8. Expos	uro contr	als/narsan	al protoc	tion					
8.1. Control pa		ois, personi	ii protec						
Substance		CASI	No		upational (lues/short			Bio	logical limit values
				I	ppm	mg/n	n ³		
-		-			-	-		No inform	nation available
Substance - name:									
EC No: -		CAS No:	-						
DNEL									
		_			lustrial			. 1	
Route of exposure:	•	Acute ect local	Acute effect syster			Chronic effect local			Chronic effect systemic
Oral	-		-			-			-
Inhalation	-		-			-			-
Dermal	-		-			_			-
Critical physical pa	rameters: s	solubility, fla	ımmabili	ty, cor	rosivity:	_			
				Co	nsumer				
Route of exposure:		Acute ect local	effe	Acutect sys	te Chroni stemic effect lo			Chronic effect systemic	
Oral	-		-			-			-
Inhalation	-		-			-			-
Dermal	-		-			-			-
PNEC									
Environmental pro	tection tar	get			PNEC				
Fresh water				No infor	mation av	/ailabl	e		
Freshwater sediments				No information available					
Marine water					No infor	mation av	/ailabl	e	
Marine sediments					No infor	mation av	/ailabl	e	
Food chain				No information available					

No information available

No information available



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Trading name:		SPERM-DIFF 2 RTU REAGENT				
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Air			No information available			
8.2.	Exposure controls					
8.2.1.	Appropriate engineering	controls	S			
	Substance/mixture related measures to prevent exponential 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:	event	No information available			
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to pre exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equipment					
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.				
8.2.2.2.	Skin protection					
0. L.L.L.			ective gloves must be according to the EU Directive 2016/425/EEC and dard EN 374.			
	Hand protection:		Glove material: nitrile rubber			
			Glove thickness: ≥0.50 mm			
			Break through time: >480 min			
	Other skin protection:		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 fo	octive full face mask (EN 136) or half mask (EN 140) equipped with a for organic vapors, type "A" (boiling point >65°C) acording to EN 7) used when concentration levels exceed GVI.			
8.2.2.4.	Thermal hazards:	No inf	formation available			
8.2.3.	Environmental exposure	controls				
	Substance/mixture related measures to prevent expo		See Section 6			
	Structural measures to pr exposure:	event	Use modern equipment.			
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.			
	Technical measures to proexposure:	event	See Section 6			

SECTION 9. Physical and chemical properties



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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	
Lover and upper explosion limit:	No information available	No information available	
Flash point:	No information available	No information available	
Auto-ignition temperature:	No information available	No information available	
Decomposition temperature:	No information available	No information available	
pH:	5.5 – 6.5	No information available	
Kinematic viscosity:	No information available	No information available	
Solubility:	No information available	No information available	
Partition coefficient n-octanol/water (log value):	No information available	No information available	
Vapour pressure:	No information available	No information available	
Density and/or relative density	No information available	No information available	
Relative vapour density:	No information available	No information available	
Particle characteristics:	No information available	No information available	

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

SECTION 11. Toxicological information



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

11.1. Informatio	n on hazard classes as	defined in Reg	ulation (EC) No 127	72/2008		
Route of exposure: Method		Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure t	Exposure time Re	
Oral exposure:	No information available	-	LD ₅₀	-		-
Dermal exposure:	No information available	-	LD ₅₀	-		-
Inhalation exposure:	No information available	-	LC ₅₀	-		-
Specific tar	get organ toxicity – si	ngle exposure (STOT SE):			
	Specifi	c effects	Target	organ		Note
Oral exposure:	No information	available	No informati		-	
Dermal exposure:	No information	available	No informati	on available	-	
Inhalation exposure	: No information	available	No informati	No information available -		
	l .		: 		1	
Aspiration	hazard:	No info	rmation available			
į I						
Irritation a	nd corrosion:					
	Exposure time	Species	Evaluation	Method		Note
Skin irritation:	-	rabbit	-			
Eye irritation:	_	rabbit	_			
,						
Sensitizatio	on					
Dermal exposure:	No information avail	able				
Inhalation exposure:	No information avail	able				
-	:					
Symptoms	related to the physica	l, chemical and	toxicological chara	acteristics		
Oral exposure:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting					
Dermal exposure:	· · · · ·	•	ure, resorption effe ngling sensation o		ely. Lon	g-term exposure



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Trading name:		SPERM-DIFF 2	RTU REAGENT	
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Inhalation expos	IIre.	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.							
Eye exposure: Direct eye co sensation.			ontact may cause slight to moderate irritation, lacrimation and burning						
Repeate	ed dose toxic	ity (sub	acute, subchro	onic, chroni	c)				
	Dose	:	Exposure time	Species	-	Method	Evaluation	Note	
Subacute oral	No inforr available	nation	No information available	No informati available	on	No information available	No informatio available	n -	
Subacute dermal	No inforr available	nation	No information available	No informati available	on	No information available	No informatio available	n -	
Subacute inhalation	No information available		No information available	No informati available	on	No information available	No informatio available	n -	
Subchronic oral	No information available		No information available	No informati available	on	No information available	No informatio available	n -	
Subchronic dermal	No inforn available	nation	No information available	No informati available	on	No information available	No informatio available	n -	
Subchronic inhalation	No inforr available	nation	No information available	No informati available	on	No information available	No informatio available	n -	
Chronic oral	No inforr available	nation	No information available	No informati available	on	No information available	No informatio available	n -	
Chronic dermal	No inforr available	nation	No information available	No informati available	on	No information available	No informatio available	n -	
Chronic inhalation	No inforn available	nation	No information available	No informati available	on	No information available	No informatio available	n -	
Specific	target organ	n tovicit	y – repeated e	ynosura (C	TOT P	E).			
Specific	Larger organ		pecific effects	Aposare (5		Target org	an	Note	
Subacute oral	No		tion available		No ii	nformation ava		-	
Subacute derma			ition available			nformation ava		-	
Subacute inhalat			ntion available			nformation ava		_	



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

Subchro	onic oral	No informat	ion available	No information available	-			
Subchro	onic dermal	No informat	ion available	No information available	-			
Subchro	onic inhalation	No informat	ion available	No information available	-			
Chronic	oral	No informat	ion available	No information available	-			
Chronic	dermal	No informat	ion available	No information available	-			
Chronic	inhalation	No informat	ion available	No information available	-			
	CMR effects (c	arcinogenicity	; mutagenicity; rep	roductive toxicity)				
	Carcinogenicit	y:	Current studies	Current studies on test animals did not indicate carcinogenic effects.				
	Mutagenicity in-vitro:		Current <i>in viti</i>	Current in vitro tests did not indicate mutagenic effects.				
	Genotoxicity:		No information	No information available				
	Mutagenicity i	n-vivo:	Current <i>in viv</i>	o tests did not indicate mutageni	c effects.			
	Germ cell muta	agenicity:	No information	ation available				
	Reproductive t	oxicity:	No toxicity or organs.	n reproductive organs was deter	mined in reproductive			
				-				
	Summary of ev	aluation of th	e CMR properties:	-				
11.2.	Information or	other hazard	s:					
11.2.1.	Endocrine disr	upting proper	ties:					
	No known end	locrine disrupt	ing properties that	affect human health.				
11.2.2.	Other informa	tions:						

SECTION 1	12.	Ecological	information
52011011		_co.og.ca.	oac.o

Dose

time

_

12.1.

toxicity

Toxicity

Exposure Acute toxicity Dose **Species** Method Evaluation Note time No information No information Fish LC_{50} 96 hours available available No information No information EC₅₀ Crustacea: 48 hours available available No information No information Algae/aquatic plants IC_{50} 8 days available available Microorganisms 72 hours LC_{50} Chronic (long-term) Exposure

Species

Method

Evaluation

Note



Value

Species

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

Trading name	e:				SPERM-DIFF	2 R	TU REAGEN	Т			
Product code		SP2-RTU		Date	Date of compilation: 14 November 2022 Version: 3						
						5 5 6 6 7 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		No			
Fish		LC ₅₀	96 hours		No information available		information ailable	informa availab		-	
Crustacea:		EC ₅₀	48 hou	ırs	No information available		information ailable	No informa availab		-	
Algae/aquatic	plants	IC ₅₀	72 hou	ırs	No information available		information ilable	No informa availab		-	
Other organisi	ms	-	-		-	-		-		-	
		and degradal	oility								
Abiot		adation									
	De	gradation ha	f-lives	Method			Evaluation			1	Vote
Marine water	No in	formation av	ailable	No information available					lable	-	
Fresh water	No in	formation av	ailable	No information available			No information available -			-	
Air	No in	formation av	ailable	No information available			No informa	tion avai	lable	-	
Soil	No in	formation av	ailable	No information available			No informa	tion avai	lable	-	
Biode	gradat	ion									
% Degradatio		Time (day	s)		Method		Evaluation			Note	
No informatio	n No	o infor	mation	No ir	nformation	N	lo information	ı N	o inforr	nation	
available	av	ailable		avail	able	a	vailable	a	vailable		
	1										
		ative potentia									
		er partition o		-							
Value		entration	рН	°(Evaluat			Note	
_	No i availab	nformation le	-	-	No information	on	No informa available	tion	-		

Method

Evaluation

Note



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Tradin	ig nar	ne:	SPERM-DIFF 2 RTU REAGENT										
Produ	ct coc	de:	SP2-F	RTU	D	ate of co	ompil	ation:	14 No	14 November 2022		Version: 3	
No info		on	No informati available		ation	ation No information available		No information available		No information available			
	Chro	onic ec	otoxicit	v									
		lue		Dose		osure ime	Spe	ecies	Met	hod	Eva	aluation	Note
Chroni	c toxic	city on	fish	LC ₅₀	No infor availa	mation able	No inforr availa	mation able	No inform availab	ation i	No nfori	mation able	_
Chroni crustac		-)	EC ₅₀	No infor availa	mation able	No inforr availa	mation able	No inform availab	ation i	No nfori ivaila	nation able	-
12.4.	Mol	oility in	soil										
	Kno	wn or _l	predicte	ed distributi	on in e	environm	ental c	ompart	ments:				
	No	inform	ation av	vailable									
	Surf	ace ter	nsion:										
	,	Value		°C	C	oncentrat	tion		Metho	od		N	ote
		rmatio lable		ormation ailable		informat iilable	ion	No inf	ormation ole	1	-		
	Ads	orptior	n / desc	orption									
Transp	ort		/D coef enry's co	ficient onstant	lc	og Kow	Εν	/aporati	on rate	Metl	hod		Note
Soil-wa	ater	No availa		formation	No ir availa	nformatio able		o inform ailable	nation	No inforr available		on -	
Water-	-air	No availa		formation	No ir availa	nformatio able		o inform ailable	nation	No inforr available		on -	
Soil-air	r	No availa		nformation	No ir availa	nformatio able		o inform ailable	nation	No inforr available	matio	on -	
12.5.				d vPvB asses	ssment								
	No	inform	ation av	/ailable									



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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	l 13. Disposal considerations					
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
	Submit for disposal to the legal Protection.	person authorized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste designation	s according to Law:				
	No information available					
13.1.3.	Waste treatment – relevant info	rmation:				
	No information available					
13.1.4.	Sewage disposal – relevant info	rmation:				
	Waste must not be disposed of	into the sewage system.				
	·					
13.1.5.	Other disposal recommendation	ns:				
	authorized by the ministry in ch	remains into the sewage system. Submit the remains to the collectors arge. Do not dispose of the packaging into the sewage system. Submit authorized by the ministry in charge. Do not dispose of in places where				
13.1.6.	Relevant Community provisions	:				
	-					
SECTION	l 14. Transport information					
	Transporting/shipment by road (A	ADR)				
UN numb	ber:	Not subject to transport regulations.				
UN prop	er shipping name:	-				
Transpor	t 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			
Packing group:		-					
Environmentally ha	zardous:	-					
Special precautions	for user:	-					
Transporti	ng/shipment by	rail (RID)					
UN number:		Not subject to transport	regulations.				
UN proper shipping	g name:	-					
Transport hazard cl	ass(es):	-					
Packing group:		-					
Environmentally ha	zardous:	-					
Special precautions	for user:	-					
Inland wat	erway transport	(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	sea (IMDG)					
UN number:		Not subject to transport	regulations.				
UN proper shipping	g name:	-					
Transport hazard cl	ass(es):	-					
Packing group:		-					
Environmentally ha	zardous:	-					
Special precautions	for user:	-					
Transporti	ng/shipment by	air (ICAO-TI/IATA-DGR)					
UN number:		Not subject to transport	regulations.				
UN proper shipping	g name:	-					
Transport hazard cl	ass(es):	-					
Packing group:		-					
Environmentally ha	zardous:	-					
Special precautions	for user:	-					
-							
Further information	n: The prod	uct is not subject to classificatio	n.				



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

SECTIO	SECTION 16. Other information			
16.1.	Indication of changes:	-		
		PBT	Stable, bioaccumulative and toxic	
		vPvB	Strongly stable and strongly bioaccumulative.	
16.2.	Abbreviations and acronyms:	LD ₅₀	Lethal dose, 50%	
		LC ₅₀	Lethal concentration, 50%	
		STOT-SE	Specific target organ toxicity - single exposure	



SAFETY DATA SHEET

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

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

ANNEX: Exposure scenario resulting to Chemical safety assessment
-



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Trading name:	SPERM-DIFF 3 RTU REAGENT			
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SECTION	ON 1: Identification of	the substar	nce/mixture	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	SPERM-D	IFF 3 RTU REA	AGENT	
	Chemical name:	-			
	Catalogue number:	SP3-RTU	SP3-RTU		
1.2.	Relevant identified use	s of the substance or mixture and uses advised against			
	Uses:	 S:		ponent of Sperm-Diff RTU kit.	
	Uses advised against:		Only the i	dentified uses are advised.	
	Reason why uses advi	sed against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Production Medical Devices and there is no reason to use it for other put		
1.3.	Details of the supplier of the safety data sheet				
	Supplier:		BioGnost Ltd		
	Telephone number: +. Fax no.: +.		Medjugorska 59, Zagreb		
			+385 1 2409997		
			+385 1 2404039		
			msds@biognost.hr		
	National contact:		-		
1.4. Emergency telephone number					
	National Protection ar	National Protection and Rescue Dire		112	
	Medical information: Other information:			+385 1 2348 342	
				-	

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



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

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

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	-				

SECTIO	ECTION 4. First aid measures						
4.1.	Description of first aid measu	ires					
	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 aid	der: Treat symptomatically.					
4.2.	Most important symptoms a	nd effects, both acute and delayed					
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.					
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Longterm exposure may cause drying, cracking and tingling sensation of skin.					
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.					



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

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

SECTIO	SECTION 6. Accidental release measures						
6.1.	Personal precautions, protect	ive 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 (s	see Section 8).					
6.2.	Environmental precautions:						
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.						
6.3.	Methods and material for containment and cleaning up						
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.					



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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.				
6.3.3.	Other information:	-				
6.4.	Reference to other 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 generati	n: Secure proper ventilation.					
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.					
	Other measures:	-					
7.1.2.	Advice on general occupational hygiene:						
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.						
7.2.	Conditions for safe storage, including any incompatibilities						
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in ventilated storage rooms, and away from sources of 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 containe tightly closed.	rs				
	Advices for storage equipment:	The storage must be made of hard material; floors mube resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.					
	Further information on storage conditions:	Do not place the unused material in the storage roand do not use empty containers for storing other chemicals. Do not store with incompatible material Section 9).					
7.3.	Specific end use(s)						



Microorganisms in sewage treatment

Soil (agricultural)

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

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Trading name:					SPE	RM-DIFF	3 RTU REAG	ENT		
Product code	: 5	SP3-RTI	J	Date of cor		mpilation:	: 14 Novem	ber 2022	Version:	4
Recor	nmenc	lations:				-				
Indus	trial se	ctor spe	cific solutio	ns:		-				
SECTION 8. Ex	kposur	e contro	ols/persona	l protec	tion					
8.1. Contr	ol para	meters								
Subst	ance		CAS N	No			exposure limit term values	Bio	logical limit valu	ıes
						ppm	mg/m³		3	
-			-			-	-	No inforn	nation available	
					1	1		•		
Substance name:	-									
EC No:	-		CAS No:	-						
DNEL										
					Inc	lustrial				
Route of expos	sure:		Acute		Acut		Chron		Chroni	
·		ette	ect local	effect sys		temic	effect lo	ocal	effect syste	emic
Oral		-		-			-		-	
Inhalation		-		-		-		-		
Dermal	.1	-	- I. I. III				-		-	
Critical physica	aı parar	neters: s	solubility, fla	mmabilit		<u> </u>				
			Acute		Acut	nsumer	Chron	ic	Chroni	<u> </u>
Route of expos	sure:		ect local	effe	ect sys		Chronic effect local		effect syste	
Oral		-		-			-		-	
Inhalation		_		-			-		_	
Dermal		-		-			-		-	
PNEC							L			
Environmental protection target PNEC										
Fresh water					No infor	mation availabl	е			
Freshwater sediments					No infor	mation availabl	e			
Marine water						No information available				
Marine sedime	ents					No information available				
Food chain						No information available				

No information available

No information available



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

SECTION 9. Physical and chemical properties



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

SECTIO	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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	n on hazard classes as	defined in Regi	ulation (EC) No 127	72/2008		
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure t	ime	Results
Oral exposure:	No information available	-	LD ₅₀	-		-
Dermal exposure:	No information available	-	LD ₅₀	-		-
Inhalation exposure:	No information available	-	LC ₅₀	-		-
Specific ta	get organ toxicity – si	ngle exposure (STOT SE):			
-		c effects		: organ		Note
Oral exposure:	No information a	available	No information		-	
Dermal exposure:	No information a	available	No information	on available	-	
Inhalation exposure	: No information a	available	No information	on available	-	
			i .		1	
Aspiration	hazard:	No infor	mation available			
Irritation a	nd corrosion:					
	Exposure time	Species	Evaluation	Method		Note
Skin irritation:	-	rabbit	-			
Eye irritation:	_	rabbit	_			
,						
Sensitization	on					
Dermal exposure:	No information avail	able				
Inhalation exposure:	No information avail	able				
	:					
Symptoms	related to the physica	l, chemical and	toxicological chara	cteristics		
Oral exposure:	Swallowing may consensation; higher	ause irritation o levels of concen g, aspiration cau	f mucosa, tingling tration may cause uses coughing, diff	sensation in th nausea, abdon	ninal pa	in and vomiting.
Dermal exposure:		•	ure, resorption effe ngling sensation o		ely. Lon	g-term exposure



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Inhalation expos	IIre.		large amounts eezing, heada	•		dequately vent	ilated perimete	er may cause
Eye exposure:		Direct eye co sensation.	ontact may cau	se slight to	mode	erate irritation,	lacrimation and	d burning
Repeate	ed dose	toxicity (sub	acute, subchro	onic, chroni	(c)			
<u> </u>		Dose	Exposure time	Species	,	Method	Evaluation	Note
Subacute oral	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Subacute dermal	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Subacute inhalation	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Subchronic oral	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Subchronic dermal	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Subchronic inhalation	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Chronic oral	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Chronic dermal	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Chronic inhalation	No i availa	nformation ble	No information available	No informati available	on	No information available	No information available	-
Specific	target (organ tovicit	y – repeated e	ynosure (S	TOT PI	E)·		
эрсспіс	target		pecific effects	Aposare (S		Target org	an	Note
Subacute oral			tion available		No in	formation avai		
Subacute derma	l	No informa	ntion available		No in	formation ava	ilable -	
Subacute inhalat	ion	No informa	ntion available		No in	formation ava	ilable -	



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Trading name:		SPERM-DIFF 3	RTU REAGENT	
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		·	<u> </u>	

nic oral nic dermal nic inhalation	No informati No informati	Offavailable	No information available	-
		on available	No information available	_
inc minaration	No informati		No information available	-
oral	No informati	on available	No information available	-
dermal	No informati	on available	No information available	-
inhalation	No informati	on available	No information available	-
CMR effects (c	arcinogenicity;	mutagenicity; rep	roductive toxicity)	
Carcinogenicity	y:	Current studies	s on test animals did not indicate ca	arcinogenic effects.
Mutagenicity i	n-vitro:	Current <i>in viti</i>	ro tests did not indicate mutageni	ic effects.
Genotoxicity:		No information	n available	
Mutagenicity i	n-vivo:	Current in viv	o tests did not indicate mutageni	c effects.
Germ cell muta	agenicity:	No information	n available	
Reproductive t	oxicity:	No toxicity or organs.	n reproductive organs was deter	mined in reproductive
Summary of ev	valuation of the	CMP properties:		
Julilliary Of Ev		Civil properties.		
Information or	other hazards	:		
Endocrine disr	upting propert	ies:		_
No known end	ocrine disrupti	ng properties that	affect human health.	
Other informat	tions:			
	dermal inhalation CMR effects (c Carcinogenicity Mutagenicity is Genotoxicity: Mutagenicity is Germ cell muta Reproductive t Summary of ex Information or Endocrine disre No known end	dermal No information	dermal No information available inhalation No information available CMR effects (carcinogenicity; mutagenicity; rep Carcinogenicity: Current studies Mutagenicity in-vitro: Current in viti Genotoxicity: No information Mutagenicity in-vivo: Current in viv Germ cell mutagenicity: No information Reproductive toxicity: No toxicity or organs. Summary of evaluation of the CMR properties: Information on other hazards: Endocrine disrupting properties that	dermal No information available No information available inhalation No information available No information available CMR effects (carcinogenicity; mutagenicity; reproductive toxicity) Carcinogenicity: Current studies on test animals did not indicate can Mutagenicity in-vitro: Current in vitro tests did not indicate mutagenic Genotoxicity: No information available Mutagenicity in-vivo: Current in vivo tests did not indicate mutagenic Germ cell mutagenicity: No information available Reproductive toxicity: No toxicity on reproductive organs was determined organs. Summary of evaluation of the CMR properties: Information on other hazards: Endocrine disrupting properties: No known endocrine disrupting properties that affect human health.

SECTION 12. Ecological information

12.1. Toxicity Exposure Acute toxicity Dose **Species** Method Evaluation Note time No information No information Fish LC_{50} 96 hours available available No information No information EC₅₀ Crustacea: 48 hours available available No information No information Algae/aquatic plants IC_{50} 8 days available available Microorganisms 72 hours LC_{50} Chronic (long-term) Exposure Dose Species Method **Evaluation** Note toxicity time



Value

Species

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

Trading nam	e:				SPERM-DIFF	3 R	TU REAGEN	T		
Product code: SP3-RTU		Date of compilation: 14 November 2022 Version: 4								
Fish		LC ₅₀	96 hou	ırs	No information available		information iilable	No information	on -	
Crustacea:		EC ₅₀	48 hours		No information available		information iilable	No information available	on -	
Algae/aquatic	plants	IC ₅₀	72 hours		No information available		information ilable	No information available	on -	
Other organis	ns	-	-		_	-		-	-	
	tence a	nd degradal adation	oility							
	Deg	radation hal	f-lives	s Method			Evaluation			Note
Marine water	No inf	No information available		No information available		No information available		ole	-	
Fresh water	No information available		ailable	No information available		No informa	tion availab	ole	-	
Air	No inf	ormation av	ailable				No informa	tion availab	ole	-
Soil	No information available			No information available No information a			tion availab	ole	_	
Biode	gradatio	on								
% Degradatio	n	Time (day	5)	Method			Evaluation		No	te
No informatio available		infori ilable	mation	n No information available			No information available		No information available	
:								i i		
		tive potentia								
		er partition o								
Value		ntration	рН	°C			Evaluat			ote
_	No in available	formation e	-	-	No information	on	No informa available	tion -		

Method

Evaluation

Note



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Trading r	ame:	SPERM-DIFF 3 RTU REAGENT										
Product o	ode:	SP3-R	RTU	D	ate of c	ompila	ition:	14 No	vember 2	2022	Vers	sion: 4
No information available		No information available		n No information available		No information available			No information available			
С	hronic ec	otoxicit	у									
	Value		Dose		osure ime	Spe	cies	Met	hod	Eva	luation	Note
Chronic to	xicity on	fish	LC ₅₀	No infor availa	mation able	No inform availal		No informavailab	ation	No information available		-
Chronic toxicity on crustacea (<i>Daphnia</i>) EC ₅₀		EC ₅₀	No No information infor		No inform availal		No informa availab	ation	No inform availal		-	
K	nown or	predicte	ed distributi railable	on in e	environm	ental co	ompart	ments:				
	urface ter											
	Value		°C	C	oncentra [.]	tion		Metho	d		N	ote
ir	No No information available available		ormation	No information No infavailable availab		formation -						
Α	dsorptior	n / deso	rption									
Transport		/D coef enry's co		log Kow		Eva	Evaporation rate		Method			Note
Soil-water No information available		No information available			No information available		No information available		n -			
Water-air	ter-air No information No information available		-			No information available						
Soil-air No information available							No infor		n -			
12.5. R	esults of	PRT and	l vPvB asses	sment								
		. 										



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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	<u>4. </u>				
	N 13. Disposal considerations					
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
13.1.1.	<u> </u>	al person authorized by the Ministry of Environmental and Nature				
	Protection.	as person dutionized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste designation	ons according to Law:				
	No information available					
13.1.3.	Waste treatment – relevant inf	formation:				
	No information available					
13.1.4.	Courage disposal relevant inf	iormation:				
13.1.4.	Sewage disposal – relevant inf Waste must not be disposed of					
	waste mast not be disposed t	into the sewage system.				
13.1.5.	Other disposal recommendation	ons:				
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.					
13.1.6.	Relevant Community provisions:					
	-					
SECTIO	N 14. Transport information					
	Transporting/shipment by road					
UN num		Not subject to transport regulations.				
······	per shipping name:	-				
Transpo	ort hazard class(es):	-				



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Trading name:		SPERM-DIFF 3	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	rail (RID)					
UN number:		Not subject to transport	regulations.				
UN proper shipping	g name:	-					
Transport hazard cl	ass(es):	-					
Packing group:		-					
Environmentally ha	zardous:	-					
Special precautions	for user:	-					
Inland wat	erway transport	(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	sea (IMDG)					
UN number:		Not subject to transport	regulations.				
UN proper shipping	g name:	-					
Transport hazard cl	ass(es):	-					
Packing group:		-					
Environmentally ha	zardous:	-					
Special precautions	for user:	-					
Transporti	ng/shipment by	air (ICAO-TI/IATA-DGR)					
UN number:		Not subject to transport	Not subject to transport regulations.				
UN proper shipping	g name:	-	-				
Transport hazard cl	ass(es):	-					
Packing group:		-					
Environmentally hazardous:		-					
Special precautions	for user:	-					
Further information	n: The prod	uct is not subject to classificatio	n.				



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

SECTIO	SECTION 16. Other information			
16.1.	Indication of changes:	-		
		PBT	Stable, bioaccumulative and toxic	
		vPvB	Strongly stable and strongly bioaccumulative.	
16.2.	Abbreviations and acronyms:	LD ₅₀	Lethal dose, 50%	
		LC ₅₀	Lethal concentration, 50%	
		STOT-SE	Specific target organ toxicity - single exposure	



SAFETY DATA SHEET

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

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

ANNEX: Exposure scenario resulting to Chemical safety assessment