

LEUKOGNOST SPE

The kit contains:

Reagent 1 (Sodium nitrite, solution)

Reagent 2 (Pararosaniline, solution)

Reagent 3 (SPE buffer)

Reagent 4 (SPE substrate)



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Trading name:	SODIUM NITRITE, SOLUTION				
Product code:	NAN-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

1.1.	Product identifier				
	Trading name:	SODIUN	и NITRITE, SOLU	ITION	
	Chemical name:	-			
	Catalogue number:	NAN-O	T-X**		
1.2.	Relevant identified uses of the substance or mixture and uses advised against			ture and uses advised against	
	Uses:		For use in cyt	ochemical diagnostics.	
	Uses advised against:		Only the iden	tified uses are advised.	
	Reason why uses advi	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes	
1.3.	Details of the supplie	r of the saf	ety data sheet		
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska !	59, Zagreb	
	Telephone number:		+385 1 2409997		
	Telephone number:		+385 1 240999	97	
	Telephone number: Fax no.:		+385 1 240999 +385 1 240403		
	•	oerson:		39	
	Fax no.:	person:	+385 1 240403	39	
1.4.	Fax no.: e-mail of competent		+385 1 240403 msds@biogno	39	
1.4.	Fax no.: e-mail of competent National contact:	number	+385 1 240400 msds@biogno	39	
1.4.	Fax no.: e-mail of competent National contact: Emergency telephone	number	+385 1 240400 msds@biogno	ost.hr	

SECTIO	SECTION 2. Hazards identification					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification according to Regula	ation (EC) No 1272	2/2008 (CLP)			
	Hazard class and category	/ code:		Hazard statements*:		
	Not identified as hazardous substance					
2.1.2.	Additional information					
	-					
*For fu	Ill text of Hazard- and EU Hazard-st	atements: see Sec	tion 16			
2.2.	Label elements					
	Product identification:	SODIUM NITRIT	TE, SOLUTION			
	Identification number:	-				
	Authorization no.:	_				
	Hazard pictograms:	-				



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	Signal word:	-		
	Hazard statements:	-		
	Precautionary statements:	-		
	Further information:	-		
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.			

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)		
7632-00-0/ 231-555-9/ 007-010-00-4	01-2119471836- 27	<5%	sodium nitrite	Ox. Sol. 3; H272 Acute Tox. 3; H301 Eyelrrit.2A; H319 Aquatic Acute 1; H400		

SECTIO	SECTION 4. First aid measures				
4.1.	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:	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 aider	: Treat symptomatically.			
4.2.	Most important symptoms and	effects, both acute and delayed			
	EUIIUMING INNSISTION.	ccording to our findings, chemical, physical and toxicological properties of ne substance have not been entirely tested.			



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	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
4.3.	Indication of any immediate	e medical attention and special treatment needed
	-	

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

SECTIO	SECTION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. 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 containr	ment and cleaning up			



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6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
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	
	-	

SECTIO	ON 7. Handling and storage				
7.1.	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.			
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.			
	Measures to protect the environment: Other measures:	Prevent spilling into the sewage system and waterways.			
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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Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection								
8.1. Control p	arameters							
Substanc	e	CAS N	No		•	exposure limit t term values	Biological limit values	
				ķ	ppm	mg/m³		
-		-			-	-	No information available	
Substance name:								
EC No: -		CAS No:	-					
DNEL								
				Ind	lustrial			
Route of	,	Acute		Acute	9	Chronic	Chronic	
exposure:	effe	ect local	effe	ct syst	temic	effect local	effect systemic	
Oral	-		-			-	-	
Inhalation	-		-			-	-	
Dermal	-		-			_	-	
Critical physical pa	arameters:	solubility, fla	mmabilit	ty, cori	rosivity:	-		
			ı	Cor	sumer			
Route of		Acute		Acute		Chronic	Chronic	
exposure:	effe	ect local	effe	effect systemic		effect local	effect systemic	
Oral	-		-			-	-	
Inhalation	-		-			-	-	
Dermal			-			-	-	
PNEC								
Environmental pro	tection tar	get			PNEC			
Fresh water					No information available			
Freshwater sediments					No information available			
Marine water					No information available			
Marine sediments						mation available		
Food chain					No information available			
Microorganisms ir	n sewage tr	eatment			No infor	mation available		
Soil (agricultural)					No information available			



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Air			No information available			
8.2.	Exposure controls					
8.2.1.	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 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 equip	oment				
8.2.2.1.	Eye and face protection:	tion: Safety glasses that stick to face (preventing splashing) visor.				
8.2.2.2.	Skin protection					
U.L.L.	Hand protection:		decetive gloves must be according to the EU Directive 2016/425/EEC and dard 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 s (EN 13034), and shoes that cover the entire foot (EN 10335).			
8.2.2.3.	Respiratory protection:	filter fo	ctive full face mask (EN 136) or half mask (EN 140) equipped with a cor organic vapors, type "A" (boiling point >65°C) acording to EN) used when concentration levels exceed GVI.			
8.2.2.4.	Thermal hazards:	No inf	ormation available			
8.2.3.	Environmental exposure	controls				
	Substance/mixture relate measures to prevent expe		See Section 6			
	Structural measures to prexposure:	event	Use modern equipment.			
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.			
	Technical measures to pr exposure:	event	See Section 6			

SECTION 9. Physical and chemical properties



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	Value	Method
Physical state:	liquid	No information available
Colour:	colourless	No information available
Odour/odour threshold:	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:	No information available	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			
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008		



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Acute toxi	city:			1	
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	e Results
Oral exposure:	No information available	-	LD ₅₀	_	_
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	_	_
Specific ta	rget organ toxicity – s	ingle exposure	(STOT SE):		
	Specific		Target organ		Note
Oral exposure:	No information		No information available	–	
Dermal exposure:	No information	available	No information available	-	
	alation exposure: No information available No information available				
Inhalation exposure	e: No information	available	available	-	
Inhalation exposure	e: No information	available		-	
•	y irritation:			-	
•			available	-	
Respirator			available	-	
Respirator	y irritation:		available	Method	Note
Respirator	y irritation: and corrosion	No inf	available ormation available		Note -
Respirator Irritation a	y irritation: and corrosion	No info	available ormation available Evaluation		
Respirator Irritation a Skin irritation:	y irritation: Ind corrosion Exposure time	No info	available ormation available Evaluation -	Method -	-
Respirator Irritation a Skin irritation:	y irritation: Ind corrosion Exposure time -	No info	available ormation available Evaluation -	Method -	-
Respirator Irritation a Skin irritation: Eye irritation: Sensitization	y irritation: Ind corrosion Exposure time -	Species	available ormation available Evaluation -	Method -	-
Respirator Irritation a Skin irritation: Eye irritation:	y irritation: Ind corrosion Exposure time	Species lable	available ormation available Evaluation -	Method -	-
Respirator Irritation a Skin irritation: Eye irritation: Sensitization Dermal exposure: Inhalation exposure:	y irritation: Ind corrosion Exposure time On No information avai No information avai	Species lable	available ormation available Evaluation -	Method - -	-
Respirator Irritation a Skin irritation: Eye irritation: Sensitization Dermal exposure: Inhalation exposure: Symptoms	y irritation: Ind corrosion Exposure time On No information avai No information avai	Species lable lable	available ormation available Evaluation	Method - -	-
Respirator Irritation a Skin irritation: Eye irritation: Sensitization Dermal exposure: Inhalation exposure: Symptoms Oral exposure:	y irritation: Ind corrosion Exposure time On No information avai No information avai	Species	available ormation available Evaluation	Method - -	-
Respirator Irritation a Skin irritation: Eye irritation: Sensitization Dermal exposure: Inhalation exposure:	y irritation: Ind corrosion Exposure time on No information avai No information avai Ro information avai No information a	Species	available ormation available Evaluation	Method - -	-



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	Dose	Exposure time	Species	Method	Evaluation	Note
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 target organ toxicity – repeated exposure (STOT RE):					
	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	-		



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Chronic	inhalation	No informat	tion available	No information available	-
	CMR effects (c	carcinogenicity	. mutagenicity	, reproductive toxicity)	
	Carcinogenicit			available data, the classification criteria	are not met.
	Mutagenicity i	in-vitro:	Based on	available data, the classification criteria	are not met.
	Genotoxicity:		Based on	available data, the classification criteria	are not met.
	Mutagenicity i			available data, the classification criteria	
	Germ cell mut			available data, the classification criteria	
	Reproductive :	toxicity:	Based on	available data, the classification criteria	are not met.
11.2	Summary of e			ties: -	
11.2.1.	Endocrine disr				
		nce/mixture ponents con ne disrupting REACH Artic Delegated regi	does not sidered to properties le 57(f) or ulation (EU) Regulation		
11.2.2.	Other informa	tions:	:		
	-				

SECTION 12. Ecological information

12.1. Toxicity

Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	_	-	-



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Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

ъ.		
RIOO	laara	Nation.
DIOU	ı c uı at	dation

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

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	рН	°C	Method	Evaluation	Note
-	No information available	_	_	No information available	No information available	-

Bioconcentration factor (BCF)



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\	√alue		Species	N	1ethod		Evaluation		Note	
	No information No informati available available		on No information available		No information available	No inform	lo information available			
	Chronic	ecotoxic	ity							
	Value		Dose	Exposure time	Spe	ecies	Method	Evalua	tion	Note
Chroni	c toxicity o	on fish	LC ₅₀	No information available	No infori availa	mation able	No information available	No inform available	nation	-
	c toxicity c cea (<i>Daphr</i>		EC ₅₀	No information available	No infori availa	mation able	No information available	No inform available	nation	-
12.4.	Mobility	, in soil								
			ted distributi	on in environr	mental o	compart	ments:			
	Known			on in environr	mental d	compart	ments:			
	Known	or predic		on in environr	mental o	compart	ments:			
	Known o	or predic rmation a tension:		On in environ		compart	ments:			Note
	Known of No infor	or predic rmation a tension: e N tion ir	available		ation			able	-	Note
	Known of No information of No	or predic rmation a tension: e N tion ir	°C lo nformation	Concentr No informa	ation		Method	able	-	Note
	No infor Surface Valu No informat available	or predic rmation a tension: e N tion ir	°C lo nformation vailable	Concentr No informa	ation		Method	able	-	Note
Transp	No information available	tension at tension: e tion ir at tension ir at tension at tensio	°C lo nformation vailable	Concentr No informa	ation	No inf	Method		thod	Note
	No information available ort	or predic rmation a tension: e Ntion ir e a	°C lo nformation vailable corption	Concentr No informavailable	ation ation	No inf	Method Formation avail		thod	
Transp	Known of No information available ort No ater No available No available No available No available No available No ater No available No	ion / des A/D coe Henry's e	°C lo nformation vailable corption efficient constant	Concentr No information available log Kow	ation ation ion No	No inf Evapo o inform	Method formation avail ration rate	Met No inform	thod	



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12.5. Results of	PBT and vPvB assessm	ent			

12.5.	Results of PBT and vPvB assessment
12.3.	The substance/mixture does not contain components considered to have endocrine disrupting properties
	according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission
	Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.6.	Endocrine disrupting properties
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7.	Other adverse effects
	No information available
	TVO INTOTITUDON AVAILABLE
SECTIO	N 13. Disposal considerations
13.1.	Waste treatment methods
13.1.	Waste deather 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:



SAFETY DATA SHEET

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

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SECTION 14. Transport information	
Transporting/shipment by road	(ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (R	IID)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (II	MDG)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-



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Special precautions for user:		-
Further information:	_	

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				

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



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Trading name:	SODIUM NITRITE, SOLUTION				
Product code:	NAN-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

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 u 1272/2008 (CLP)	sed to derive the classification for mixture according to Regulation (EC)		
Classifi	cation	Classification procedure		
_		-		
16.5.	Relevant H statements (numb	er and full text)		
	272	May intensify fire; oxidizer.		
	H: 301	Toxic if swallowed.		
	319	Causes serious eye irritation.		
	400	Very toxic to aquatic life.		
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.		

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Exposure scenario resulting to Chemical safety assessment



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Trading name:		PARAROSANILINE, S	OLUTION		
Product code:	PARA-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

1.1	Product identifier				
	Trading name:	PARAROSA	PARAROSANILINE, SOLUTION		
	Chemical name:	-	-		
	Catalogue number:	PARA-OT-X	RA-OT-X**		
1.2	Relevant identified us	Relevant identified uses of the substance or mixture and uses advised against			
	Uses:		For use i	in cytochemical diagnostics.	
	Uses advised against:		Only the	identified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplier of the safety data sheet				
	Supplier:		BioGnost Ltd.		
	Address:	Address:		Medjugorska 59, Zagreb	
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent p	person:	msds@biognost.hr		
	National contact:		-		
1.4	Emergency telephone	Emergency telephone number			
	National Protection a	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ION 2. Hazards identification				
2.1	Classification of the substance or mixture				
2.1.1	Classification according to Regu	ulation (EC) No 12	272/2008 (CLP)		
	Hazard class and catego	ory code:		Hazard statements*:	
	Acute Tox. 4		H302		
	Carc. 1B		H350		
2.1.2.	Additional information				
	-				
*For ful	ll text of Hazard- and EU Hazard-	statements: see S	ECTION 16		
2.2	Label elements				
	Product identification:	PARAROSANILIN	NE, SOLUTION		
	Identification number: -				
	Authorization number:	-			



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Trading name:		PARAROSANILINE, SOLUTION				
Product code:	PARA-OT-X**	Date of compilation:	21 Dec 2022	Version:	2	

	Hazard pictograms:	GHS07 GHS08
	Signal word:	Danger
	Hazard statements:	H302 Harmful if swallowed. H350 May cause cancer.
	Precautionary statements:	 P201 Obtain special instructions before use. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352 IF ON SKIN: Wash with plenty of water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P501 Dispose of contents/container in accordance with local regulations.
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	Results of PBT and vPvB ass PBT or a vPvB.	

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)		
111-46-6/ 203-872-2/ 603-140-00-6	01-2119457857-21- XXXX	80 – 100 %	diethylene glycol	Acute Tox. 4; H302		
569-61-9/ 209-321-2/ 611-031-00-X	-	4 – 5 %	4,4'-(4-iminocyclohexa-2,5-dienylidenemethylene) dianiline hydrochloride	Carc. 1B; H350		



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Trading name:	PARAROSANILINE, SOLUTION				
Product code:	PARA-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	_
4.2	Most important symptoms and ef	fects, both acute and delayed
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Danger of gastric perforation.
4.3	Indication of any immediate medi	cal attention and special treatment needed

SECTIO	CTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Water spray, alcohol-resistant foam, dry chemical or carbon dioxide.			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the substance or mixture				
	Hazardous combustion products: No information available				
5.3	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.				
5.4	Additional information				



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Trading name:		PARAROSANILINE, S	OLUTION	_	
Product code:	PARA-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

Do not contaminate the environment with extinguishing media.

SECTIO	ON 6. Accidental release meas	ures			
6.1	Personal precautions, protective	ve equipment and emergency procedures			
6.1.1.	For non-emergency personnel	For non-emergency personnel			
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.			
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:				
	Use protective equipment; in c (see Section 8).	ase of inadequate ventilation use adequate airways protective equipment			
6.2	Environmental precautions:				
	Do not dispose of in sewage, or Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National rate (NPRD) on 112.			
6.3	Methods and material for cont	ainment and cleaning up			
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.			
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. 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 involved materials with water.			
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).			
6.4	Reference to other sections				
	See Section 7 for information of	on safe handling.			
	See Section 8 for information of	on personal protection equipment.			
	See Section 13 for disposal info	ormation.			

SECTIO	SECTION 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat.			
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.			
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.			



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Trading name:	PARAROSANILINE, SOLUTION				
Product code:	PARA-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

I						
	Other measures:	-				
7.1.2.	Advice on general occupational hygiene:					
	Do not eat, drink or smoke in the workspace. Th	noroughly wash hands after work and before eating.				
7.2	Conditions for safe storage, including any incom	npatibilities				
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers at temperatures ranging from +2 to +8 °C.				
	Packaging materials:	Manufacturer's original packaging. Avoid metal containers.				
	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 10).				
7.3	Specific end use(s)					
	Recommendations:	-				
	Industrial sector specific solutions:	-				

Industrial	Industrial sector specific solutions: -						
SECTION 8. Expos	SECTION 8. Exposure controls/personal protection						
8.1 Control p	8.1 Control parameters						
Substance	Substance CAS No values/short terr			•	Biological limit values		
				рр	m	mg/m³	
-			-	-		-	No information available
				•			
Substance name:	_						
EC No:	-	CAS No	:				
DNEL							
				Indus	trial		
Route of exposure:	Acı effect		Acut			Chronic effect local	Chronic effect systemic
Oral	-		-		-		-
Inhalation	-		-		-		-
Dermal	-		-		-		-



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			, flammability, co	nsume	:		
Route of		Acute	Acute				Chronic
exposure	e: 	effect local	effect system	ic	effect local	eff	ect systemic
Oral		-	-	-		-	
Inhalation	n	-	-	-		-	
Dermal		-	-			-	
PNEC				1			
Environm	nental prot	ection target		PNEC			
Fresh wat	ter			no inf	ormation available	!	
Freshwate	er sedimer	nts		no inf	ormation available	ļ	
Marine w	ater			no inf	ormation available		
Marine se	ediments			no inf	ormation available	!	
Food cha	iin			no inf	ormation available)	
Microorg	anisms in	sewage treatment		no information available			
Soil (agrid	cultural)			no information available			
-			no information available				
Air				no int	ormation available		
Air 8.2	Exposu	ure controls		no inf	ormation available		
	•	ure controls priate engineering	controls	no inf	ormation available		
8.2	Approp		d measures to	Use th	ne product in well ctive equipment. C	ventilated rooms	•
8.2	Approp Substa	priate engineering ince/mixture relate it exposure during ural measures to pr	d measures to identified uses:	Use the protection works	ne product in well ctive equipment. C	ventilated rooms o not eat, drink	•
8.2	Substa preven Structu exposu	priate engineering ince/mixture relate it exposure during ural measures to pr ure: isational measures	d measures to identified uses:	Use the protein works In accordance	ne product in well ctive equipment. D pace.	ventilated rooms o not eat, drink on 7. order to reduce	or smoke in the
8.2	Substa preven Structu exposu Organi exposu	priate engineering ince/mixture relate it exposure during ural measures to pr ure: isational measures	d measures to identified uses: revent to prevent	Use the protein works. In accompanies of the security of the	ne product in well ctive equipment. D pace. ordance with Sect	ventilated rooms o not eat, drink on 7. order to reduce rocess. e ventilation in o	or smoke in the other worker's order to keep
8.2	Substa preven Structu exposu Organi exposu	priate engineering ince/mixture relate it exposure during ural measures to pr ure: isational measures ure:	d measures to identified uses: revent to prevent event exposure:	Use the protein works. In accompanies of the security of the	ne product in well ctive equipment. E pace. ordance with Sect nization of work in nce during work per proper workspacentration levels in a	ventilated rooms o not eat, drink on 7. order to reduce rocess. e ventilation in o	or smoke in the other worker's order to keep
8.2 8.2.1.	Substa prevent Structu exposu Organi exposu Techni	priate engineering Ince/mixture relate It exposure during Irral measures to pr Irre: Isational measures Irre: Irre: Irrai measures Irre:	d measures to identified uses: revent to prevent event event event safety levels of	Use the protein works. In accompanies of concession co	ne product in well ctive equipment. E pace. ordance with Sect nization of work in nce during work per proper workspacentration levels in a	ventilated rooms to not eat, drink on 7. order to reduce rocess. e ventilation in coir below permitted and showering. EN 166) or visor otective gas mas	or smoke in the other worker's order to keep ted levels. Secure in case of lower
8.2 8.2.1.	Substa prevent Structurexposus Organiexposus Technia	priate engineering Ince/mixture relate It exposure during Irral measures to pr Irre: Isational measures Irre: Ical measures to pr Irral measures to pr Irral measures Irral measures to pr	d measures to identified uses: revent to prevent event event event safety levels of	Use the protein works. In accompanies of concession co	ne product in well ctive equipment. E pace. ordance with Sect nization of work in nce during work pe proper workspacentration levels in a ns for rinsing eyes that stick to face entration in air; proper workspacentration in air; pr	ventilated rooms to not eat, drink on 7. order to reduce rocess. e ventilation in coir below permitted and showering. EN 166) or visor otective gas mas	or smoke in the other worker's order to keep ted levels. Secure in case of lower



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Trading name:	PARAROSANILINE, SOLUTION				
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	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Not required under normal conditions of use. Use suitable respiratory protective device when high concentrations are present.
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.
	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	Visual inspection
	Colour:	purple	Visual inspection
	Odour/odour threshold:	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:	No information available	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



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Trading name:	PARAROSANILINE, SOLUTION				
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	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

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 (room temperature).			
10.3	Possibility of hazardous reactions:	No dangerous reactions known.			
10.4	Conditions to avoid:	No information available			
10.5	Incompatible materials:	No information available			
10.6	Hazardous decomposition products:	No information available			

SECTIO	N 11. Toxico	ological info	ormation						
11.1 Information on toxicological effects									
	Acute toxic	ity:							
Route o		Method	Species	Do	se LD ₅₀ /LC ₅₀ or ATE _{mix}	E	xposure tim	e Results	
Oral:		-	No information	on	-		information lable	-	
Dermal		-	No information	on	-	No information available		-	
Inhalati	on:	_	No informatio	on	_		information lable	-	
	Specific tar		xicity – single ex pecific effects	posure (S		et organ		Note	
Oral:		No informa	tion available		No information available -				
Dermal		No informa	tion available		No information available -			-	
Inhalati	on:	No informa	tion available	No information available -					
				·					
	Aspiration l	nazard:		No information available.					
	Irritation an	d corrosion							
		Ехро	osure time	Speci	es Evalu	ation	Method	Note	
Skin		_		_	_		_	_	



Serious eye

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

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damage/irritation	-	-	-	-	–	
Sensitization						
Skin sensitization:	-					
Respiratory sensitization:	-					

Symptoms related to the physical, chemical and toxicological characteristics						
Oral exposure:	Harmful if swallowed.					
Dermal exposure:	No information available.					
Inhalation exposure:	No information available.					
Eye exposure:	No information available.					

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
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	-



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Trading nar	me:	PARAROSANILINE, SOLUTION						
Product co	de: PA	ARA-OT-X**	Date of compilation:	21 Dec 2022	Version:	2		

Chronic inhalatic	on	No information available	No information available	No information available	No information available	No information available	on	-
	Specific	target organ toxic	ity – reneated ex	vnosure (STOT	RE)∙			
	эреспіс	target organ toxic	Specific effec	·	Target o	rgan		Note
Subacut	e oral	No inform	nation available		No information		_	Note
	e dermal		nation available		No information		_	
	e inhalati		nation available		No information		_	
Subchro			nation available		No information		_	
	nic derm		nation available		No information		-	
	nic inhali		nation available		No information		_	
Chronic			ation available		No information		-	
Chronic	dermal	No inform	ation available		No information	n available	_	
Chronic	inhalatio	n No inform	nation available		No information	n available	-	
	Carcinogenicity: Mutagenicity in vitro: Genotoxicity: Mutagenicity in vivo: Germ cell mutagenicity: Reproductive toxicity:			carcinoger Current in No inform Current in No inform No toxicity reproduct	udies on test animalic effects. vitro tests did notation available. vivo tests did notation available. y on reproductive ive organs.	ot indicate n	nutage	enic effects.
44.0	properti	es:		No inform	ation available.			
11.2.		tion on other haza						
11.2.1.	The sub compon disruptin Article regulation	ne disrupting propostance/mixture considered to the properties accused for Common (EU) 2017/210 for (EU) 2018/605 accused for (EU) 2018/605 accused for EU) 2018/605 accuse	loes not conta o have endocri ording to REAC ission Delegato 0 or Commissio	ne CH ed on				



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Trading name:	PARAROSANILINE, SOLUTION					
Product code:	PARA-OT-X**	Date of compilation:	21 Dec 2022	Version:	2	

11.2.2.	Other informations:
	-

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

12.2 Persist	tence and degradability			
	3 ,			
Abioti	c degradation	:		,
	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-



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				. a.g.c . = c				
Trading name:	PARAROSANILINE, SOLUTION							
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Soil	No information available	No information No	information					

Soil	No	information	available	No ir availa	nformation able	_	information -	
Bioc	legrada	tion						
% Degrada	ation	Time (days)		Method		Evaluation	Note
No informati available	on	No ir available	nformation	No ii	nformation able		information	
12.3 Bioa	ccumul	ative potentia	al					
Octa	anol-wa	ter partition o	coefficient (log Ko	w)			
Value	Cond	centration	рН	°C	Method	I	Evaluation	Note
	NI- :£	ormation			No informat	ion	No information	

Bioconce	ntration factor (BCF)			
Value	Species	Method	Evaluation	Note
No information available	No information available	n No information available	No information available	No information available

Chronic ecotoxicit	ty					
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4	Mobility in soil
	Known or predicted distribution in environmental compartments:
	No information available



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	Surf	ace tensio	n:					
	١	/alue	°C	Concentration	n Met	hod	Note	
	No No information available available		No information available	n No informat available	No information available			
	Ads	orption / o	desorption					
Transpo	ort	-	coefficient 's constant	log Kow	Evaporation rate	e Metl	nod	Note
Soil-wat	ter	No available	information	No information available	No information available	No inforr available	mation	-
Water-a	air	No available	information	No information available	No information available	No inforr available	mation	-
Soil-air		No available	information	No information available	No information available	No inforr available	mation	-
12.5.			and vPvB asses	ssment				
12.6.	End	ocrine disi	rupting properti	es				
	accc	ording to F	REACH Article 5	not contain compo 7(f) or Commission evels of 0.1% or hi	n Delegated regul			srupting properties or Commission
12.7.	Oth	er adverse	effects					
	No i	nformatio	n available					
			consideration	S				
13.1	W	aste treati	ment methods					
13.1.1.	Pr	oduct/Pac	kaging disposa	l:				
		bmit for o	lisposal to the l	egal person autho	rized by the Minis	try of Enviro	nmental	and Nature



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	No information available	
13.1.3.	Waste treatment – relevar	nt information:
	No information available	
13.1.4.	Sewage disposal – relevar	nt information:
	Waste must not be dispos	sed of into the sewage system.
13.1.5.	Other disposal recommen	dations:
	authorized by the ministry	duct's remains into the sewage system. Submit the remains to the collectors in charge. Do not dispose of the packaging into the sewage system. Submit ectors authorized by the ministry in charge. Do not dispose of in places where
13.1.6.	Relevant Community prov	risions:
	-	
SECTIO	N 14 TRANSPORT INFORM	ATION
	Transporting/shipment by r	oad (ADR)
UN num	nber:	Not subject to transport regulations
UN prop	per shipping name:	-
Transpo	rt hazard class(es):	-
Packing	group:	-
Environr	mentally hazardous:	-
Special	precautions for user:	-
	Transporting/shipment by r	ail (RID)
UN num	nber:	Not subject to transport regulations
UN prop	per shipping name:	-
Transpo	rt hazard class(es):	-
Packing	group:	-
Environr	mentally hazardous:	-
Special	precautions for user:	-
	Inland waterway transport (ADN)
UN num	nber:	Not subject to transport regulations
UN prop	per shipping name:	-
Transpo	rt hazard class(es):	-
Packing	group:	-



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

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



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	None	
15.2	Chemical safety assessmen	nt
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
	Information according 199 guideline)	9/13/EC about limitation of emissions of volatile organic compounds (VOC-
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);

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



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Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)					
Classification		Classification procedure			
		-			
Rele	evant H statements (numb	per and full text)			
H: 302		Harmful if swallowed.			
2	350	May cause cancer.			
Trai	ning advice:	-			
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.			
	127 Rele H:	Relevant H statements (numl H: 302 350 Training advice:			

ANNEX: Exposure scenario resulting to chemical safety assessment
-



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Trading name:	SPE BUFFER				
Product code:	FOP-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

1.1.	Product identifier				
	Trading name:	SPE BL	JFFER		
	Chemical name:	-			
	Catalogue number:	FOP-O	T-X**		
1.2.	Relevant identified use	es of the s	ubstance or mix	ture and uses advised against	
	Uses:		For use in cyt	ochemical diagnostics.	
	Uses advised against:		Only the iden	tified uses are advised.	
	Reason why uses advis	sed	The product is intended for use only as an <i>in vitro</i> diagnostic med device, registered at the Agency for Medicinal Products and Medi Devices and there is no reason to use it for other purposes		
1.3.	Details of the supplier	of the saf	ety data sheet		
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska !	59, Zagreb	
	Telephone number:		+385 1 240999	97	
	Fax no.:		+385 1 24040	39	
		erson:	+385 1 240403 msds@biogno		
	Fax no.:	erson:			
1.4.	Fax no.: e-mail of competent p		msds@biogno		
1.4.	Fax no.: e-mail of competent p National contact:	number	msds@biogno		
1.4.	Fax no.: e-mail of competent p National contact: Emergency telephone	number	msds@biogno	ost.hr	

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 catego	ory code:	Hazard statements*:				
	Not identified as hazardous sub	stance.	-				
2.1.2.	Additional information						
	-						
*For fu	ll text of Hazard- and EU Hazard-:	statements: see S	ection 16				
2.2.	Label elements						
	Product identification:	SPE BUFFER					
	Identification number:	-					
	Authorization no.:	-					
	Hazard pictograms:	-					



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	Signal word:	-		
	Hazard statements:	-		
	Precautionary statements:	-		
	Further information:	-		
2.3.	Other hazards			
	Endocrine Disrupting Propertie	es:		
	No known endocrine disrupting properties			
	Results of PBT and vPvB assessment : According to the results of its assessment, this substance is not PBT or a vPvB.			

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	-			

SECTION 4. First aid measures			
4.1.	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:	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 and effects, both acute and delayed		
	Following inhalation:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.	
	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.	



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	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.		
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.		
4.3.	Indication of any immediate medical attention and special treatment needed			
	-			

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

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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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	
	-	

SECTIO	ON 7. Handling and storage					
7.1.	Precautions for safe handling					
7.1.1.	Protection measures					
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.				
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.				
	Measures to protect the environment: Other measures:	Prevent spilling into the sewage system and waterways.				
7.1.2.	Advice on general occupational hygiene:					
	Do not eat, drink or smoke in the workspace. T	horoughly wash hands after work and before eating.				
7.2.	Conditions for safe storage, including any inco	mpatibilities				
	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)					
	Recommendations:	-				
	Industrial sector specific solutions:	-				



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SECTION 8. Exposur	e contr	ols/person	al protec	tion			
8.1. Control para	meters	T					
Substance				•	exposure limit t term values	Biological limit values	
					ppm	mg/m³	
-		-			-	-	No information available
Substance - name:							
EC No: -		CAS No:	-				
DNEL							
				Inc	dustrial		
Route of	A	Acute		Acut	e	Chronic	Chronic
exposure:	effe	ect local	effe	ct sys	temic	effect local	effect systemic
Oral	-		-			-	-
Inhalation	-		-			-	-
Dermal	-		-			<u> </u>	-
Critical physical parar	meters: s	solubility, fla	mmabilit	y, cor	rosivity:	-	
	1		_	Co	nsumer		
Route of		Acute		Acut		Chronic	Chronic
exposure:	effe	ect local	effe	ct sys	temic	effect local	effect systemic
Oral	-		-			-	-
Inhalation	-		-			-	-
Dermal	-		-			-	-
PNEC					I		
Environmental protect	tion tar	get			PNEC		
Fresh water			No information available				
Freshwater sediments			No information available				
Marine water			No information available				
Marine sediments			No information available				
Food chain				No information available			
Microorganisms in sewage treatment				No information available			
Soil (agricultural)					No information available		
Air					No infor	mation available	



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8.2.	Exposure controls					
8.2.1.	Engineering measures					
	massires to prevent evacuire		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	ment				
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) visor.				
8.2.2.2.	Skin protection	\\				
	Hand protection:	1	ard 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 s (EN 13034), and shoes that cover the entire foot (EN 10335).			
8.2.2.3.	Respiratory protection:	filter fo	ctive full face mask (EN 136) or half mask (EN 140) equipped with a cor organic vapors, type "A" (boiling point >65°C) according to EN) used when concentration levels exceed GVI.			
8.2.2.4.	Thermal hazards:	No inf	ormation 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 prevent exposure:		See Section 6			

SECTIO	SECTION 9. Physical and chemical properties					
9.1.	Information on basic physical and chemical properties					
		Value	Method			



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Physical state:	liquid	No information available
Colour:	colourless	No information available
Odour/odour threshold:	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:	No information available	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	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				

SECTIO	SECTION 11. Toxicological information				
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				



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Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	_	LD ₅₀	_	_
Dermal exposure:	xposure: No information available		LD ₅₀	-	-
Inhalation exposure:			LC ₅₀	-	-
Specific tar	get organ toxicity – s	ingle exposure	(STOT SE):		
· ·	Specific	effects	Target organ		Note
Oral exposure:	No information		No information available	_	
Dermal exposure:	No information	available	No information available	-	
Inhalation exposure:	No information	available	No information available	-	
Irritation ar	nd corrosion				
	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	-	-	-	-
Eye irritation:	-	-	-	-	-
Sensitizatio	n				
Dermal exposure:	No information avai	lable			
Dermai exposure.	No information available				
Inhalation exposure:	No information avai	lable			
Inhalation exposure:			d toxicological characterist	ics	
Inhalation exposure:		al, chemical an	d toxicological characterist	ics	
Inhalation exposure: Symptoms	related to the physic	al, chemical an vailable	d toxicological characterist	ics	
Inhalation exposure: Symptoms Oral exposure:	related to the physic No information a No information a	al, chemical an vailable vailable	d toxicological characterist	ics	

Repeated dose toxicity (subacute, subchronic, chronic)



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	Dose	Exposure time	Species	Method	Evaluation	Note
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	-

apeeme target	organ toxicity – repeated expo		
	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	-



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Chronic	inhalation	No informat	ion available	No information available	-
	CMR effects (c	arcinogenicity	. mutagenicity	, reproductive toxicity)	
	Carcinogenicit			available data, the classification criteria a	are not met.
	Mutagenicity <i>in-vitro</i> : Based on available data,			available data, the classification criteria a	are not met.
	Genotoxicity: Base			available data, the classification criteria a	are not met.
	Mutagenicity in-vivo: Based			available data, the classification criteria a	
	3 ,			available data, the classification criteria a	
	Reproductive toxicity: Based on available data, the classification criteria are not met.				are not met.
11.2	Summary of e			ties: -	
11.2.1.	Endocrine disr				
	The substant contain communication have endocring to Commission E 2017/2100 or (EU) 2018/60 higher.	ponents con ne disrupting REACH Artic Delegated regu Commission	properties le 57(f) or ulation (EU) Regulation		
11.2.2.	Other informa	tions:			
	_				

SECTION 12. Ecological information

12.1. Toxicity

Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	_	-	-



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Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

D: 1		
RION	aaraa	dation
DIOU	cyrac	aation

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

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	рН	°C	Method	Evaluation	Note
-	No information available	_	_	No information available	No information available	-

Bioconcentration factor (BCF)



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	Value		Species	Me	Method		Note		
No information available		No avai	informati lable	on No inform available			No information available		ilable
	Chronic	ecotoxi	city						
	Value		Dose	Exposure time	Species	Method	Evaluati	ion	Note
Chroni	ic toxicity (on fish	LC ₅₀	No information available	No information available	No information available	No informa available	ation	-
	ic toxicity o		EC ₅₀	No information available	No information available	No information available	No informa available	ation	-
12.4	N.A I- 1114	,							
12.4.		y in soil or predi	cted distributi	on in environm	ental compart	tments:			
12.4.	Known	or predi		on in environm	ental compart	tments:			
12.4.	Known o	or predi rmation	available	on in environm	ental compart	tments:			
12.4.	Known on the No info	or predi rmation tension	available						Note
12.4.	Known o	or predi rmation tension ie	available :	Concentrat No informat available	ion	Method formation avail	able		Note
Transp	No info Surface Valu No informa available	or predi rmation tension ie e tion / de	available :	Concentrat	ion No inf	Method formation avail	able	-	Note
	No informa available Adsorpt	or predi rmation tension ie ition i e i	available :	Concentrat No informat available	ion No inf	Method formation avail ration rate		- nod	
Transp	No informal available Adsorpt ater Adsorpt No	or predi rmation tension ie ition / de A/D co Henry's	available C No information available esorption pefficient s constant	Concentrate No informate available log Kow	ion No inf Evapo No inform available	Method formation avail ration rate	Meth No informa	- nod ation	Note



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Trading name:		SPE BUFF	ER	
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:				

12.5.	Results of PBT and vPvB assessment
	No information available
12.6.	Endocrine disrupting properties
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7.	Other adverse effects
	No information available
SECTIO	N 13. Disposal considerations
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
1212	
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
13.1.1.	Waste must not be disposed of into the sewage system.
	Tradition in a subposed on lines and some age systems
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-
SECTIO	N 14. Transport information
	Transporting/shipment by road (ADR)



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UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (R	ID)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IN	MDG)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-



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Further information:	-

15.1.	Safety, health and environ	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations					
	Authorization and/or rest	rrictions 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 (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain				
		dangerous substances, mixtures and articles (Annex XVII);				
	Information according 19 guideline)	999/13/EC about limitation of emissions of volatile organic compounds (VOC-				
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act				
15.2.	Chemical safety assessme	ent				
	None					

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



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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)	used to derive the classification for mixture according to Regulation (EC)		
Classifi	cation	Classification procedure		
_		-		
16.5.	Relevant H statements (numb	per 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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1.1	Product identifier			and of the company/undertaking	
	Trading name:	SPE SUBSTF	RATE		
	Chemical name:	-			
	Catalogue number:	NASD-OT->	NASD-OT-X**		
1.2	Relevant identified us	es of the subs	tance or n	nixture and uses advised against	
	Uses:		For use	n cytochemical diagnostics.	
	Uses advised against:		Only the	identified uses are advised.	
	Reason why uses advi	sed against:	The product is intended for use only as an <i>in vitro</i> diagnor diagnost: medical device, registered at the Agency for Medicinal P Medical Devices and there is no reason to use it for other		
1.3	Details of the supplier	Details of the supplier of the safety data sheet			
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997 +385 1 2404039 <u>msds@biognost.hr</u>		
	Telefax.:				
	e-mail of competent p	person:			
	National contact:		_		
1.4	Emergency telephone	Emergency telephone number			
	National Protection a	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ON 2. Hazards identification					
2.1	Classification of the substance or mixture					
2.1.1	Classification according to Reg	Classification according to Regulation (EC) No 1272/2008 (CLP)				
	Hazard class and catego	ory code:	Hazard statements*:			
	Acute Tox. 4		H312			
	Eye Irr. 2		H319			
	Acute Tox. 4		H332			
	Repr. 1B		H360D			
2.1.2.	Additional information					
	-					
*For fu	Ill text of Hazard- and EU Hazard-	statements: see S	ECTION 16			
2.2	Label elements					
	Product identification: SPE SUBSTRATE					



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	Identification number:	-			
	Authorization number:	-			
	Hazard pictograms:	GHS08 GHS07			
	Signal word:	Danger			
	Hazard statements:	 H312 Harmful in contact with skin. H319 Causes serious eye irritation. H332 Harmful if inhaled. H360D May damage the unborn child. 			
	Precautionary statements:	P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P302 + P352 IF ON SKIN: Wash with plenty of soap and water P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332 + P313 If skin irritation occurs: Get medical advice/attention. P337 + P313 If eye irritation persists: Get medical advice/attention.			
	Supplemetal hazard information (EU):	-			
2.3	Other hazards	Other hazards			
	Endocrine Disrupting Prope				
	No known endocrine disruption Results of PBT and vPvB ass PBT or a vPvB.	sessment: According to the results of its assessment, this substance is not a			

SECTION 3. Composition/information on ingredients						
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)		
68-12-2/ 200-679-5/ 616-001-00-X	-	95 – 100 %	dimethyl formamide	Acute Tox. 4; H312 Eye Irr. 2; H319 Acute Tox. 4; H332 Repr. 1B; H360D		

SECTION 4. First aid measures

4.1 Description of first aid measures



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Foll Foll Self	lowing inhalation: lowing skin contact: lowing eye contact:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen. Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain. 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. Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large		
Foll Self	lowing eye contact:	water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain. 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. Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a		
Foll Self		least 20 minutes. If the symptoms remain, immediately call in ophthalmologist. Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a		
Self	lowing ingestion:	, , ,		
		quantities, transport the afflicted person to the hospital.		
4.2 Mo	f-protection of the first aider:	-		
	st important symptoms and effe	ects, both acute and delayed		
Foll	owing inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.		
Foll	owing skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.		
Foll	owing eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.		
Foll	owing ingestion:	Danger of gastric perforation.		
4.3 Indi	ication of any immediate medic	cal attention and special treatment needed		

SECTI	SECTION 5. Firefighting measures						
5.1	Extinguishing media						
	Suitable extinguishing media:	Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2).					
	Unsuitable extinguishing media:	Do not use a heavy water stream.					
5.2	Special hazards arising from the substance or mixture						
	Hazardous combustion products:	Carbon oxides, sodium oxides. Combustible. Development of hazardous combustion gases or vapours possible in the event of fire.					
5.3	Advice for firefighters						
	Use a self-contained open-circuit	compressed air breathing apparatus and fireproof clothing.					
5.4	Additional information	Additional information					
	Do not contaminate the environm	ent with extinguishing media.					

SECTION 6. Accidental release measures



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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. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.				
	Emergency procedures:	Mark the area using proper signs.				
6.1.2.	For emergency responders:					
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).					
6.2	Environmental precautions:					
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.					
6.3	Methods and material for con	tainment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.				
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. 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 involved materials with water.				
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).				
6.4	Reference to other sections					
	See Section 7 for information	on safe handling.				
	See Section 8 for information	on personal protection equipment.				
	See Section 13 for disposal inf	formation				

SECTIO	SECTION 7. Handling and storage						
7.1	Precautions for safe handling						
7.1.1.	Protection measures						
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat.					
	Measures to prevent aerosol and dust generation:	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 was	sh hands after work and before eating.					



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7.2	Conditions for safe storage, including any incon	npatibilities
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers at temperatures ranging from +2 to +8 °C.
	Packaging materials:	Manufacturer's original packaging. Avoid metal containers.
	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 10).
7.3	Specific end use(s)	
_	Recommendations:	-
	Industrial sector specific solutions:	-

	ON 8. Exposi			nal pr	otection				
8.1	Control parameters								
Substance C		CA			Occupational exposure limit values/short term values			Biological limit values	
					m	r	ng/m³		
-			-	-			-	-	
			•			•		•	
Substa	nce name:	-							
EC No:	:	-	CAS No	:	-				
DNEL									
					Indu	strial			
Route	of	Ac	ute		Acute		Ch	ronic	Chronic
expos	ure:	effect	: local	effe	ct systemic		effe	ct local	effect systemic
Oral		-		-		-			-
Inhalat	tion	-		-		-			-
Derma	al	-		-		-			-
Critica	l physical par	ameters:	solubility,	flamm	ability, corro	sivity:		-	
					Cons	umer			



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Route of exposure		Acute effect local	Acute effect system	Chronic c effect local	Chronic effect systemic	
Oral		-	-	-	-	
Inhalation	1	-	-	-	-	
Dermal		-	-	-	-	
PNEC						
Environm	ental prot	ection target		PNEC		
Fresh water				no information available		
Freshwater sediments				no information available		
Marine water				no information available		
Marine sediments				no information available		
Food chain				no information available		
Microorganisms in sewage treatment				no information available		
Soil (agricultural)				no information available		
Air				no information available		
	_					
	Appro	re controls		Use the product in well ver	ntilated rooms. Use personal	
	Approp Substa preven	priate engineering nce/mixture relate It exposure during	d measures to identified uses:	•	ntilated rooms. Use personal not eat, drink or smoke in the	
	Approp Substa preven	priate engineering nce/mixture relate It exposure during Ural measures to pr	d measures to identified uses:	protective equipment. Do I	not eat, drink or smoke in the	
8.2.1.	Substa preven Structu exposu	priate engineering nce/mixture relate at exposure during ural measures to pr ure: isational measures	d measures to identified uses: event	protective equipment. Do not workspace. In accordance with Section	not eat, drink or smoke in the 7. der to reduce other worker's	
	Substa preven Structu exposu Organi exposu	priate engineering nce/mixture relate at exposure during ural measures to pr ure: isational measures	d measures to identified uses: event to prevent	protective equipment. Do not workspace. In accordance with Section Organization of work in organization of work processes were proper workspace with Secure proper with Secure proper workspace with Secure proper with Secure proper with Secure proper with Secure proper workspace with Secure proper with Secure pro	not eat, drink or smoke in the 7. der to reduce other worker's cess. ventilation in order to keep below permitted levels. Secure	
	Substa preven Structu exposu Organi exposu	priate engineering nce/mixture relate at exposure during ural measures to pr ure: isational measures ure:	d measures to identified uses: event to prevent event event event event event event event event event exposure:	protective equipment. Do now workspace. In accordance with Section Organization of work in organization of work processes with Secure proper workspace workspace workspace with Secure proper with Secure proper with Secure proper workspace with Secure proper w	not eat, drink or smoke in the 7. der to reduce other worker's cess. ventilation in order to keep below permitted levels. Secure	
8.2.1.	Substa prevent Structu exposu Organi exposu Techni	priate engineering nce/mixture relate it exposure during ural measures to pr ure: isational measures ure: cal measures to pr	d measures to identified uses: event to prevent event event event Safety levels of	protective equipment. Do now workspace. In accordance with Section Organization of work in organization of work in organization of work processed by the secure proper workspace workspace workspace workspace workspace or concentration levels in air less stations for rinsing eyes and glasses that stick to face (EN	not eat, drink or smoke in the 7. der to reduce other worker's ress. ventilation in order to keep below permitted levels. Secure ad showering. I 166) or visor in case of lower ctive gas mask that covers the	
3.2.1. 3.2.2. 3.2.2.1.	Substa prevent Structu exposu Organi exposu Techni Person	priate engineering nce/mixture relate at exposure during ural measures to pr ure: isational measures ure: cal measures to pr al protection equip	d measures to identified uses: event to prevent event event event Safety levels of	protective equipment. Do now workspace. In accordance with Section Organization of work in organization of work in organization work processed by the secure proper workspace workspace workspace workspace workspace in air lations for rinsing eyes an organization of secure proper workspace workspace.	not eat, drink or smoke in the 7. der to reduce other worker's ress. ventilation in order to keep below permitted levels. Secure ad showering. I 166) or visor in case of lower ctive gas mask that covers the	
8.2.1.	Substa prevent Structu exposu Organi exposu Techni Person Eye and Skin pr	nce/mixture relate of exposure during ural measures to proceed to proceed the exposure during ural measures to proceed measures to proceed measures to proceed measures to proceed proced face proced face proced measures to face proced face proced measures to proced face proced face proced measures to proced face proced face proced face proced measures to proced face proced fac	d measures to identified uses: event to prevent event event event Safety levels of entire event	protective equipment. Do now workspace. In accordance with Section Organization of work in organization of work in organization work processed by the secure proper workspace workspace workspace workspace workspace in air lations for rinsing eyes an organization of secure proper workspace workspace.	der to reduce other worker's cess. ventilation in order to keep below permitted levels. Secure ad showering. I 166) or visor in case of lower ctive gas mask that covers the of concentration in air.	



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8.2.2.3.	Respiratory protection:	Not required under normal conditions of use. Use suitable respiratory protective device when high concentrations are present.				
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.				
	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	Visual inspection
	Colour:	colourless	Visual inspection
	Odour/odour threshold:	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:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient noctanol/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



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9.2	Other information
	-

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 (room temperature).		
10.3	Possibility of hazardous reactions:	No dangerous reactions known.		
10.4	Conditions to avoid:	No information available		
10.5	Incompatible materials:	No information available		
10.6	Hazardous decomposition products:	No information available		

11.1	Information	on toxicolo	gical effects					
	Acute toxici		<u>g </u>					
Route exposu		Method	Species	Dos	e LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure t	n	Results
Oral:		_	No information available		-	No information	on	-
Derma	l:	-	No information available		-	No information available No information		-
Inhalat	ion:	-	No information available		-	No information available		-
	Specific targ		xicity – single expos pecific effects	sure (ST	OT SE): Target	organ		Nete
			pecific effects		ranget	organ		Note
Oral:		No informa	tion available		No information	available		Note
Derma		No informa	tion available		No information	available available	-	Note
		No informa	tion available		No information	available available	-	Note
Derma		No informa No informa No informa	tion available tion available tion available		No information	available available	-	Note
Derma	ion:	No informa No informa No informa	tion available tion available tion available		No information No information No information	available available	-	Note
Derma	ion:	No informa No informa No informa nazard:	tion available tion available tion available		No information No information No information	available available	-	Note
Derma	ion: Aspiration h	No informa No informa No informa nazard:	tion available tion available tion available		No information No information No information ation available.	available available available	-	Note



Serious eye

SAFETY DATA SHEET

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damage/irritation -		-	-	-	-
Sensitization					
Skin sensitization:	-				
Respiratory sensitization:	_				

Symptoms re	elated to the physical, chemical and toxicological characteristics				
Oral exposure:	Oral exposure: No information available.				
Dermal exposure:	No information available.				
Inhalation exposure:	No information available.				
Eye exposure:	No information available.				

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure .·	Species	Method	Evaluation	Note
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	-



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Chronic inhalation	No availa	information able	No information available	No information available	No information available	No informatio available	on -	
Speci	fic target	organ toxicit	y – repeated e	xposure (STOT	RE):			
		3	Specific effec		Target o	rgan	Not	e
Subacute oral		No informa	tion available		No information		-	
Subacute derr	ubacute dermal No information available			No information	n available	-		
Subacute inhalation No informa		tion available		No information	n available	-		
Subchronic oral No informa		tion available		No information	n available	-		
Subchronic de	rmal	No informa	tion available		No information	n available	-	
Subchronic in	nalation	No informa	tion available		No information	n available	-	
Chronic oral		No informa	tion available		No information	n available	-	
Chronic derma	al	No informa	tion available		No information	n available	-	
Chronic inhala	tion	No informa	tion available		No information	n available	-	
CMR effects (carcinogenicity; mutagenicity) Carcinogenicity: Mutagenicity in vitro: Genotoxicity: Mutagenicity in vivo: Germ cell mutagenicity: Reproductive toxicity: Summary of evaluation of the CM properties:		No inform No inform No inform No inform May dama No inform	ation available. ation available. ation available. ation available. ation available. age the unborn clation available. ation available.	nild.				
		other hazard						
		upting prope						
component disrupting Article 57 regulation		onsidered to perties acco or Commis) 2017/2100	hes not contained have endocrification to REAC sion Delegated or Commission levels of 0.1%	ne CH ed on				
11.2.2. Othe	rinformat	ions:						



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12.1 Toxicit	у									
Acute (short-te toxicity	rm)	Dose	Exposur time	e	Species	Method	Evalı	uation	Note	
Fish		LC ₅₀	-	-		-	-		-	
Crustacea:		EC ₅₀	-	-		-	-		-	
Algae/aquatic բ	olants	IC ₅₀	-	-		-	-		-	
Other organism	าร	-	-	-		-	-		-	
Chronic (long-t toxicity	erm)	Dose	Exposur time	e	Species	Method	Evalı	uation	Note	
Fish		LC ₅₀	96 hours		lo information vailable	No information available	No inforr availa	mation ible	-	
Crustacea:		EC ₅₀	48 hours		lo information vailable	No information available	No inforr availa	mation ible	-	
Algae/aquatic p	olants	IC ₅₀	72 hours		No information vailable	No information available	No inforr availa	mation ible	-	
Other organism	าร	-	-	-		-	-		-	
12.2 Persist	ence a	nd degradal	oility							
Abioti	c degra	ndation								
	De	gradation h	alf-lives	2	Method	Evaluatio	n		Note	
Marine water	No ir	nformation a	available		nformation lable	No informatio available	n	-		
Fresh water	No ir	nformation a	available		nformation lable	No information available		-		
Air	No ir	nformation a	available		nformation lable	No information available		-		
Soil	No information available			No information No info available availabl		n	-			
Biode	gradatio	on				l .		1		
% Degradation Time (days)		days)		Method	Evaluatio	n		Note		
% Degradation	No information available No information					n				



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									······································			•
	:											
12.3	Bioaccum	ulative p	otential									
	Octanol-w	ater pa	tition coe	efficient	(log Kow)		i				
Valu	e Co	ncentra	tion	рН	°C	M	ethod	Evalu	ation		Note	
_	-		-		-	_		-		-		
	Bioconcen	tration			_					0 0 0 0 0		
	'alue		Species			Method		Evaluati			Note	
No into	rmation le	No availal		rmation	No info		on	No informati available	on	_		
					<u> </u>							
								!				
	Chronic ed	otoxicit	У									
	i		_	Exp	osure	C		N 4 - 4 a	F I	-4:	Niete	
	Value		Dose	t	ime	Sp	ecies	Method	Evalu	ation	Note	
.		C. I	1.6	No		No		No · · · · · ·	No			
Chronic	toxicity on	tisn	LC ₅₀	infor avail	mation able	availa	mation able	information available	informa availab		-	
<i>-</i>				No		No		No	No			
	toxicity on ea (<i>Daphnia</i>	·)	EC ₅₀	l l	mation		mation	information	informa		-	
		,		avail	able	availa	able	available	availab	le		
12.4	Mobility in		1 11									
	Known or	-		ution in (environm	nental d	compart	ments:				
	No inform		/ailable									
	Surface te	nsion:	0.0					NA 11 1			NI i	
	Value	N.I.	°C		oncentra	ition	**************************************	Method			Note	
	No information	No n inf	ormation		informa	tion		ormation	-			
	available		ailable	ava	ailable		availak	ole				



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	Adsorption / desorption					
Transpor	t A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note	
Soil-wate	No information available	No information available	No information available	No information available	-	
Water-air	r No information available	No information available	No information available	No information available	-	
Soil-air	No information available	No information available	No information available	No information available	-	
12.5.	Results of PBT and vPvB asses	ssment				
	No information available					
12.6.	Endocrine disrupting properti	es				
	No information available					
12.7.	Other adverse effects					
	No information available					
SECTION	l 13. Disposal consideration	s				
13.1	Waste treatment methods					
13.1.1.	Product/Packaging disposa	l:				
	Submit for disposal to the learning Protection.	egal person autho	rized by the Ministr	y of Environmental	and Nature	
13.1.2.	Waste codes/waste designa	itions 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:					



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	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.			
13.1.6.	Relevant Community provisions:			
	-			
SECTION	I 14. Transport information			
	Transporting/shipment by roa	d (ADR)		
UN numb	oer:	Not subject to transport regulations		
UN prope	er shipping name:	-		
Transpor	t hazard class(es):	-		
Packing o	group:	-		
Environm	nentally hazardous:	-		
Special p	recautions for user:	-		
	Transporting/shipment by rail	(RID)		
UN numb	per:	Not subject to transport regulations		
UN prope	er shipping name:	-		
Transpor	t hazard class(es):	-		
Packing o	group:	-		
Environm	nentally hazardous:	-		
Special p	recautions for user:	-		
	Inland waterway transport (AD	DN)		
UN numb	oer:	Not subject to transport regulations		
UN prope	er shipping name:	-		
Transpor	t hazard class(es):	-		
Packing o	group:	-		
Environm	nentally hazardous:	-		
Special p	recautions for user:	-		
Transporting/shipment by sea ((IMDG)		
UN number:		Not subject to transport regulations		
UN prope	er shipping name:	-		
Transpor	t hazard class(es):	-		
Packing group:		-		
Environm	nentally hazardous:	-		
Special p	recautions for user:	-		



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

.1 Safety, health and en	vironmental regulations/legislation specific for the substance or mixture
EU regulations	
Authorization and/or	restrictions of use
Authorizations:	-
Restrictions:	-
Other EU regulations	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);



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	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment	
	None	

SECTION	ON 16	. Other information			
16.1		ication of changes:	-		
16.2	Abb	previations 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 used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
Classification			Classification procedure		
_			-		
16.5.	Relevant H statements (number and full text)				
		312	Harmful in contact with skin.		
	H:	319	Causes serious eye irritation.		
		332	Harmful if inhaled.		
		360D	May damage the unborn child.		
16.6.	Trai	Training advice: -			
16.7.	Fur	ther 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.		



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ANNEX: Exposure scenario resulting to chemical safety assessment						
-						