

Trading name:	SODIUM NITRITE, SOLUTION				
Product code:	NAN-OT-X**	Date of compilation:	24 June 2021	Version:	1

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	SODIUM NITRITE, SOLUTION
	Chemical name:	-
	Catalogue number:	NAN-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use 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:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	SODIUM NITRITE, SOLUTION
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	-
	Signal word:	-

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	Hazard statements:	-
	Precautionary statements:	-
	Supplemental hazard information (EU):	-
2.3	Other hazards	
	-	

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

SECTION 4. First aid measures		
4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	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.

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	Following ingestion:	Danger of gastric perforation.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Water spray, foam, dry powder, CO ₂ or alcohol resistant foam.
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Nitrogen oxides (NO _x). During heating or in case of fire poisonous gases are produced.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, 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.	Bundling, 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.

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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 information.	

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 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 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:	-

SECTION 8. Exposure controls/personal protection	
8.1	Control parameters

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Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	-

Substance name:	-			
EC No:	-	CAS No:	-	

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC

Environmental protection 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

8.2	Exposure controls
8.2.1.	Appropriate engineering controls

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	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	Protective nitrile gloves, >0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	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

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid	Visual inspection
	Colour:	Colourless	Visual inspection
	Odour:	No information available	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available

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	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	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

SECTION 11. Toxicological information					
11.1	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results

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Oral:	-	No information available	-	No information available	-
Dermal:	-	No information available	-	No information available	-
Inhalation:	-	No information available	-	No information available	-

Specific target organ toxicity – single exposure (STOT SE):

	Specific effects	Target organ	Note
Oral:	No information available	No information available	-
Dermal:	No information available	No information available	-
Inhalation:	No information available	No information available	-

Aspiration hazard:	No information available.
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Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-

Sensitization

Skin sensitization:	-
Respiratory sensitization:	-

Symptoms related to the physical, chemical and toxicological characteristics

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 time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-

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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	-

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	Specific target organ toxicity – repeated exposure (STOT RE):					
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	Specific effects		Target organ		Note	
Subacute oral	No information available		No information available		-	
Subacute dermal	No information available		No information available		-	
Subacute inhalation	No information available		No information available		-	
Subchronic oral	No information available		No information available		-	
Subchronic dermal	No information available		No information available		-	
Subchronic inhalation	No information available		No information available		-	
Chronic oral	No information available		No information available		-	
Chronic dermal	No information available		No information available		-	
Chronic inhalation	No information available		No information available		-	

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	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)					
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	Carcinogenicity:		No information available.			
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	Mutagenicity <i>in vitro</i> :		No information available.			
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	Genotoxicity:	No information available.
	Mutagenicity <i>in vivo</i> :	No information available.
	Germ cell mutagenicity:	No information available.
	Reproductive toxicity:	No information available.
	Summary of evaluation of the CMR properties:	No information available.
11.2	Practical experiences:	
	Classification observations:	-
	Other observations:	-
11.3	General notes:	
	-	

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	-	-
Crustacea:	EC ₅₀	48 hours	-	-	-	-
Algae/aquatic plants	IC ₅₀	4 days	-	-	-	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
12.2	Persistence and degradability					
	Abiotic degradation					

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

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

12.3	Bioaccumulative potential					
	Octanol-water partition coefficient (log Kow)					
Value	Concentration	pH	°C	Method	Evaluation	Note
-	-	-	-	-	-	-

	Bioconcentration factor (BCF)			
Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

	Chronic ecotoxicity					
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	No information	No information	No information	-

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		available	available	available	available	
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12.4 Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

	Value	°C	Concentration	Method	Note
	No information available	No information available	No information available	No information available	-

Adsorption / desorption

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	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 assessment

No information available

12.6 Other adverse effects

No information available

SECTION 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:

Packaging that contains residual hazardous substances or is contaminated with hazardous substances

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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.
13.1.6.	Relevant Community provisions:
	-

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 (RID)
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 (IMDG)

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

SECTION 15. Regulatory information	
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations:
	-
	Restrictions:
	-
	Other EU regulations:
	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives

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	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment	
	None	

SECTION 16. Other information				
16.1	Indication of changes:		-	
16.2	Abbreviations and acronyms:		PBT	Stable, bioaccumulative and toxic
			vPvB	Strongly stable and strongly bioaccumulative.
			LD ₅₀	Lethal dose, 50%
			LC ₅₀	Lethal concentration, 50%
			TCOJ	Specific target organ toxicity - single exposure
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)			
	H:	H272	May intensify fire; oxidizer.	
		H301	Toxic if swallowed.	
		H319	Causes serious eye irritation.	
		H400	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.	

ANNEX: Exposure scenario resulting to chemical safety assessment
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Trading name:	PARAROSANILINE, SOLUTION				
Product code:	PARA-OT-X**	Date of compilation:	25 June 2021	Version:	1

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	PARAROSANILINE, SOLUTION
	Chemical name:	-
	Catalogue number:	PARA-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use 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:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Acute Tox. 4	H302
	Carc. 1B	H350
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	PARAROSANILINE, SOLUTION
	Identification number:	-
	Authorization number:	-

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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.
Supplemental hazard information (EU):	-
2.3	Other hazards
	-

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	>50%	diethylene glycol	Acute Tox. 4; H302
569-61-9/ 209-321-2/ 611-031-00-X	-	<10%	C.I. Basic Red 9	Carc. 1B; H350

SECTION 4. First aid measures	
4.1	Description of first aid measures
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.

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	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	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 medical attention and special treatment needed	
	-	

SECTION 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	
	Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).

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	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 containment and cleaning up	
6.3.1.	Bundling, 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 information.	

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 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 at temperatures ranging from +2 to +8 °C.

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	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:	-

SECTION 8. Exposure controls/personal protection				
8.1	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m³	
-	-	-	-	No information available
Substance name:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

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PNEC		
Environmental protection 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
8.2	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	Protective nitrile gloves, >0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	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

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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

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid	Visual inspection
	Colour:	Purple	Visual inspection
	Odour:	No information available	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	-		

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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

SECTION 11. Toxicological information					
11.1	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	No information available	-	No information available	-
Dermal:	-	No information available	-	No information available	-
Inhalation:	-	No information available	-	No information available	-
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
	Aspiration hazard:		No information available.		
	Irritation and corrosion				
Exposure time		Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-
	Sensitization				
Skin sensitization:	-				

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Respiratory sensitization:	-
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Symptoms related to the physical, chemical and toxicological characteristics
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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)
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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
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Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

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CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)
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Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.
Mutagenicity <i>in vitro</i> :	Current in vitro tests did not indicate mutagenic effects.
Genotoxicity:	No information available.
Mutagenicity <i>in vivo</i> :	Current in vivo tests did not indicate mutagenic effects.
Germ cell mutagenicity:	No information available.
Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.

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Summary of evaluation of the CMR properties:	No information available.
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11.2	Practical experiences:
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Classification observations:	No information available
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Other observations:	No information available
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11.3	General notes:
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SECTION 12. Ecological information

12.1	Toxicity
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Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
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Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
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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 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	-

Biodegradation

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

12.3 Bioaccumulative potential

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Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

Bioconcentration factor (BCF)						
Value	Species		Method	Evaluation	Note	
No information available	No	information available	No information available	No information available	No information available	

Chronic ecotoxicity						
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						
Surface tension:						
Value	°C	Concentration	Method		Note	
No information available	No information available	No information available	No information available		-	

Adsorption / desorption						
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note

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Soil-water	No information available	No information available	No information available	No information available	-
Water-air	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 assessment
	No information available
12.6	Other adverse effects
	No information available

SECTION 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
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

SECTION 14 TRANSPORT INFORMATION

Trading name:	PARAROSANILINE, SOLUTION				
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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 (RID)	
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 (IMDG)	
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 (ICAO-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:	-

SECTION 15. Regulatory information		
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment	
	None	

SECTION 16. Other information		
16.1	Indication of changes:	-

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16.2	Abbreviations and acronyms:		PBT	Stable, bioaccumulative and toxic
			vPvB	Strongly stable and strongly bioaccumulative.
			LD ₅₀	Lethal dose, 50%
			LC ₅₀	Lethal concentration, 50%
			TCOJ	Specific target organ toxicity - single exposure
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)			
	H:	H302	Harmful if swallowed.	
		H350	May cause cancer.	
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
-

Trading name:	SPE BUFFER			
Product code:	FOP-OT-X**	Date of compilation:	14 July 2021	Version: 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	SPE BUFFER
	Chemical name:	-
	Catalogue number:	FOP-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use 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:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

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

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	Hazard statements:	-
	Precautionary statements:	-
	Supplemental hazard information (EU):	-
2.3	Other hazards	
	-	

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

SECTION 4. First aid measures		
4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	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 medical attention and special treatment needed	

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Product code:	FOP-OT-X**	Date of compilation:	14 July 2021	Version:	1

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

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, 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.	Bundling, 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	

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See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

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 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 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:	-

SECTION 8. Exposure controls/personal protection				
8.1	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	

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-	-	-	-	No information available
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Substance name:	-				
EC No:	-	CAS No:	-		

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC

Environmental protection 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

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8.2 Exposure controls

8.2.1. Appropriate engineering controls

Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
Structural measures to prevent exposure:	In accordance with Section 7.

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	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	Protective nitrile gloves, >0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	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

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid	Visual inspection
	Colour:	Colourless	Visual inspection
	Odour:	No information available	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point;	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available

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	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log K _{ow}):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	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

SECTION 11. Toxicological information					
11.1	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	No information available	-	No information available	-
Dermal:	-	No information available	-	No information available	-

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Inhalation:	-	No information available	-	No information available	-	
	Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects		Target organ		Note	
Oral:	No information available		No information available		-	
Dermal:	No information available		No information available		-	
Inhalation:	No information available		No information available		-	
	Aspiration hazard:		No information available.			
	Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note	
Skin corrosion/irritation:	-	-	-	-	-	
Serious eye damage/irritation	-	-	-	-	-	
	Sensitization					
Skin sensitization:	-					
Respiratory sensitization:	-					
	Symptoms related to the physical, chemical and toxicological characteristics					
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 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	-

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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	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.
Mutagenicity <i>in vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.
Genotoxicity:	No information available.
Mutagenicity <i>in vivo</i> :	Current <i>in vivo</i> tests did not indicate mutagenic effects.

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	Germ cell mutagenicity:	No information available.
	Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.
	Summary of evaluation of the CMR properties:	No information available.
11.2	Practical experiences:	
	Classification observations:	No information available
	Other observations:	No information available
11.3	General notes:	
	-	

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	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	-	-	-	-	-	-

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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	-
Biodegradation						
% Degradation	Time (days)		Method		Evaluation	Note
No information available	No information available		No information available		No information available	-
12.3 Bioaccumulative potential						
Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-
Bioconcentration factor (BCF)						
Value	Species		Method		Evaluation	Note
No information available	No information available		No information available		No information available	No information available
Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note

Trading name:	SPE BUFFER				
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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					
Surface tension:					
	Value	°C	Concentration	Method	Note
	No information available	No information available	No information available	No information available	-

Adsorption / desorption

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	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 assessment

No information available

12.6 Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1 Waste treatment methods

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13.1.1. Product/Packaging disposal:

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	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

SECTION 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 (RID)
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

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UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

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

Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

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

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	Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment	
	None	

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

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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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ANNEX: Exposure scenario resulting to chemical safety assessment
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Trading name:	SPE SUBSTRATE				
Product code:	NASD-OT-X**	Date of compilation:	24 June 2021	Version:	1

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	SPE SUBSTRATE
	Chemical name:	-
	Catalogue number:	NASD-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use 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:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Acute Tox. 4	H312
	Eye Irrit. 2	H319
	Acute Tox. 4	H332
	Repr. 1B	H360D
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	SPE SUBSTRATE
	Identification number:	-

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	Authorization number:	-
	Hazard pictograms:	  GHS07 GHS08
	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.
	Supplemental hazard information (EU):	-
2.3	Other hazards	
	-	

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	-	≤ 100 %	dimethyl formamide	Acute Tox. 4 (Dermal); H312 Eye Irrit. 2; H319 Acute Tox. 4 (Inhalation); H332 Repr. 1B; H360D

SECTION 4. First aid measures		
4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.

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	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	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 medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO ₂).
	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	
	Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).

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	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 containment and cleaning up	
6.3.1.	Bundling, 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 information.	

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 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 at temperatures ranging from +2 to +8 °C.

Trading name:	SPE SUBSTRATE				
Product code:	NASD-OT-X**	Date of compilation:	24 June 2021	Version:	1

	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:	-

SECTION 8. Exposure controls/personal protection				
8.1	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	-
Substance name:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Trading name:	SPE SUBSTRATE				
Product code:	NASD-OT-X**	Date of compilation:	24 June 2021	Version:	1

PNEC		
Environmental protection 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
8.2	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	Protective nitrile gloves, >0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	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

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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

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid	Visual inspection
	Colour:	Colourless	Visual inspection
	Odour:	No information available	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	-		

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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

SECTION 11. Toxicological information					
11.1	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	No information available	-	No information available	-
Dermal:	-	No information available	-	No information available	-
Inhalation:	-	No information available	-	No information available	-
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
	Aspiration hazard:		No information available.		
	Irritation and corrosion				
Exposure time		Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-
	Sensitization				
Skin sensitization:		-			

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Respiratory sensitization:	-
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Symptoms related to the physical, chemical and toxicological characteristics
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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)
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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
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Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
Carcinogenicity:	No information available.
Mutagenicity <i>in vitro</i> :	No information available.
Genotoxicity:	No information available.
Mutagenicity <i>in vivo</i> :	No information available.
Germ cell mutagenicity:	No information available.
Reproductive toxicity:	No information available.
Summary of evaluation of the CMR properties:	
No information available.	

11.2	Practical experiences:
	Classification observations: -
	Other observations: -
11.3	General notes:
	-

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	-	-	-	-	-
Crustacea:	EC ₅₀	-	-	-	-	-
Algae/aquatic plants	IC ₅₀	-	-	-	-	-
Other organisms	-	-	-	-	-	-

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

12.2 Persistence and degradability

Abiotic degradation

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

Biodegradation

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

12.3 Bioaccumulative potential

Octanol-water partition coefficient (log K_{ow})

Value	Concentration	pH	°C	Method	Evaluation	Note
-	-	-	-	-	-	-

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Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

Chronic ecotoxicity						
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						
Surface tension:						
Value	°C	Concentration	Method	Note		
No information available	No information available	No information available	No information available	-		

Adsorption / desorption					
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	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 assessment					
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	No information available
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12.6	Other adverse effects
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	No information available
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SECTION 13. Disposal considerations

13.1	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
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	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
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13.1.2.	Waste codes/waste designations according to Law:
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	No information available
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13.1.3.	Waste treatment – relevant information:
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	No information available
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13.1.4.	Sewage disposal – relevant information:
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	Waste must not be disposed of into the sewage system.
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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.
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13.1.6.	Relevant Community provisions:
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SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
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UN number:	Not subject to transport regulations
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UN proper shipping name:	-
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Transport hazard class(es):	-
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Packing group:	-
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Environmentally hazardous:	-
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Special precautions for user:	-
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	Transporting/shipment by rail (RID)
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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:	-

	Inland waterway transport (ADN)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

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

	Transporting/shipment by air (ICAO-TI/IATA-DGR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

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

Trading name:	SPE SUBSTRATE				
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	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment	
	None	

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

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	H:	H312 H319 H332 H360D	Harmful in contact with skin. Causes serious eye irritation. Harmful if inhaled. May damage the unborn child.
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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