

Trade name:	BIOCLEAR NEW				
Product code:	BCN-X**	Date of compilation:	15 Feb 2019	Version:	5

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	BioClear New
	Chemical name:	-
	Catalogue number:	BCN-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Xylene substitute for tissue processing, deparaffinization and clearing.
	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 numbers	
	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:	Warning statements*:
	Aspir. Tox. 1	H304
2.1.2.	Additional information	
	EUH066	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	BioClear New
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	
	GHS08
Signal word:	Danger
Hazard statement:	H304 May be fatal if swallowed and enters airways. EUH066 Repeated exposure may cause skin dryness or cracking.
Precautionary statements:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P331 Do NOT induce vomiting. P370+P378 In case of fire: Use water fog, foam, dry chemical or carbon dioxide (CO ₂) for extinction. P403+P235 Store in a well-ventilated place. Keep cool.
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)
-/ 920-901-0/ -	01-2119456810-40	100%	Hydrocarbons, C11- C13, isoalkanes, <2% aromatics	Aspir. tox. 1; H304 EUH066

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. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation.

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	Following skin contact:	Remove contaminated clothing. Thoroughly wash with water and soap for 15 minutes.
	Following eye contact:	Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open. Contact a physician if irritation occurs.
	Following ingestion:	DO NOT induce vomiting. Seek immediate medical attention.
	Self-protection of the first aider	-

4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.
	Following skin contact:	Prolonged and/or repeated exposure to low viscosity content may cause skin dryness or cracking. May be irritating to the eyes, nose, throat and lungs.
	Following eye contact:	Eye irritation may occur during exposure to vapor concentrations above recommended level.
	Following ingestion:	If swallowing occurs, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.
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
	Unsuitable extinguishing media:	Straight streams of water
5.2.	Special hazards arising from the substance or mixture	
	Hazardous by products of fire:	Smoke, fume, incomplete combustion products, carbon oxides.
5.3.	Advice for firefighters	
	Evacuate the area. Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing). Use water spray to cool fire exposed surfaces and to protect personnel.	
5.4.	Additional information	
	-	

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

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	Protective equipment:	When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus.
	Accident prevention methods:	Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks.
	Emergency procedures:	Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection.
6.1.2.	For emergency responders:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112).
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use tools that cause sparks.
	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:	

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	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating. Avoid skin contact.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in a cool and well-ventilated place. Keep away from heat and direct solar radiation.
	Packaging materials:	Teflon, polypropylene, stainless steel, carbon steel.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed. Store in a cool, well-ventilated area.
	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:	Suitable materials and coating are teflon, polypropylene, polyethylene, stainless steel, carbon steel. Unsuitable materials and coatings include ethylene propylene diene monomer (EPDM), natural rubber, polystyrene, butyl rubber.
7.3.	Specific end use(s)	
	Recommendations:	This product attracts static electricity that may cause electrical sparking (ignition source) that may ignite flammable vapors of the liquid. The liquid is usually an isolator if its conductivity level is under 100 pS/m. It is considered a semiconductor that attracts static electricity if its conductivity level is less than 10,000 pS/m. Regardless of the type of the liquid (isolator or semiconductor), precautions are the same. Numerous factors, such as the liquid temperature, contaminants, antistatic additives and filtration may severely influence the liquid conductivity.
	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	
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	-	171*	1200*	No information available
* Source - material safety data sheet provided by the raw materials supplier				
Substance:	-			
EC No:	-	CAS No:	-	
DNEL				

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Industrial				
Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer				
Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
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

Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment. Wash hands after handling the product and before eating and/or drinking.
Structural measures to prevent exposure:	Adequate ventilation should be provided so that exposure limits are not exceeded. Use explosion-proff ventilation equipment.
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	See Section 7.2

8.2.2. Personal protection equipment:

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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:	In case prolonged or repeated contact with the product, use nitril rubber protective gloves (EN 374).
	Other skin protection:	Wear full protective suit that protects from chemicals (EN 340) and shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values (or because of inadequate ventilation), use full gas mask (EN 136) equipped with a recommended filter type A.
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	No information available
	Colour:	colourless	No information available
	Odour:	faint	No information available
	Odour 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:	170 - 250 °C	No information available
	Flash point:	62 °C	No information available
	Evaporation rate:	0,05 (n-Butyl acetate = 1)	No information available
	Flammability (solid, gas):	No information available	No information available

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	Upper/lower flammability or explosive limits:	lower: 0.6 upper: 7.0	No information available
	Vapour pressure:	0.04 kPa (0.3 mm Hg) at 20 °C	No information available
	Vapour density:	> 1 at 101 kPa (Air = 1)	No information available
	Relative density	0.731 – 0.851 (15 °C)	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	Negligible	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	> 200 °C	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	1.3 cSt (1.3 mm ² /sec) at 20 °C 2.5 cSt (2.5 mm ² /sec) at 20 °C	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:	No information available
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:	Hazardous polymerization will not occur.
10.4.	Conditions to avoid:	Open flames and high energy ignition sources.
10.5.	Incompatible materials:	Strong oxidants.
10.6.	Hazardous decomposition products:	Product decomposition will not occur at ambient temperature.

SECTION 11. Toxicological information					
11.1.	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	LD ₅₀ > 5000 mg/kg	-	Minimal toxicity.
Dermal:	No information available	rabbit	LD ₅₀ > 5000 mg/kg	-	Minimal toxicity.

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Inhalation:	No information available	rat	LC ₅₀ > 5000 mg/kg	4 h	Minimal toxicity.
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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: Insignificant danger at normal handling temperature.

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	No information available	rabbit	Not irritating.	OECD	-
Serious eye damage/irritation	No information available	rabbit	Not irritating.	not specified	-

Sensitization

Skin sensitization:	Not expected to be a skin sensitizer.
Respiratory sensitization:	Not expected to be a respiratory sensitizer.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	If swallowing occurs, aspiration of the vomit may also occur and cause chemical pneumonitis or pulmonary oedema.
Dermal exposure:	Prolonged and/or repeated exposure to low viscosity content may cause irritation and dermatitis, skin drying or cracking.
Inhalation exposure:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.
Eye exposure:	Eye irritation may occur during exposure to vapor concentrations above recommended level.

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	-

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:	No carcinogenicity studies were made, but since the product is not mutagenic and causes a minimal level of toxicity, it can be assumed that chronic exposure will not cause tumors.

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	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:	No information available
	Other observations:	No information available
11.3. General notes:		
	Vapour concentration above recommended exposure levels are irritating to the eyes and the respiratory tract, may cause headaches and dizziness, are anesthetic may have other central nervous system effects. Prolonged and/or repeated skin contact with low viscosity materials may defat skin resulting in possible irritation and dermatitis. Small amounts of liquid aspirated into the lungs during ingestion or from vomiting may cause chemical pneumonitis or pulmonary edema.	

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	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	No information available	No information available	-	-
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	No information available

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Crustacea:	EC ₅₀	48 hours	No information available	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	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
No information available	No information available	-	-	No information available	No information available	No information available

Bioconcentration Factor (BCF)

Value	Species	Method	Evaluation	Note
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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	Not expected.
Chronic toxicity on crustacea (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	Not expected.

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:					
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
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. 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.
13.1.2.	Waste codes/waste designations according to Law:
	European Waste Code: 08 XX XX These codes are assigned based upon the most common uses for this material and may not reflect contaminants resulting from actual use. Waste producers need to assess the actual process used when generating the waste and its contaminants in order to assign the proper waste disposal code(s).
13.1.3.	Waste codes/waste designations according to Law:
	Incinerating the product at high temperatures is recommended in order to avoid incomplete combustion products.
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Empty Container Warning: Empty containers may contain residue and can be dangerous. Do not attempt to refill or clean containers without proper instructions. Empty drums should be completely drained and safely stored until appropriately reconditioned or disposed. Empty containers should be taken for recycling, recovery or disposal through suitably qualified or licensed contractor and in accordance with governmental regulations. Do not pressurise, cut, weld, braze, solder, drill, grind or expose such containers to heat, flame, sparks, static electricity or other sources of ignition. They may explode and cause injury or death.
13.1.6.	Relevant Community provisions:
	-
SECTION 14. Transport information	

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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:	-
Environmental hazards:	-
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:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
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:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 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:	-
Environmental hazards:	-

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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	
	Authorisations and/or restrictions on use	
	Authorisations:	-
	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 of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on 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 vPvB LD ₅₀ LC ₅₀ STOT-SE	Stable, bioaccumulative and toxic Strongly stable and strongly bioaccumulative. Lethal dose, 50% Lethal concentration, 50% 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: 304 (EUH066)	May be fatal if swallowed and enters airways. Repeated exposure may cause skin dryness or cracking.	
16.6.	Training advice:	-	
16.7.	Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.	

ANNEX: Exposure scenario resulting to Chemical safety assessment	
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Trade name:	BIOFIX				
Product code:	BF-X**	Date of compilation:	23 May 2019	Version:	3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	BIOFIX
	Chemical name:	-
	Catalogue number:	BF-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Methyl alcohol-based fixative for cryostat sections.
	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 numbers	
	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 statement*:
	Flam. liq. 2	H225
	Acute Tox. 3	H301
	Acute Tox. 3	H311
	Skin Irr. 2	H315
	Eye Irr. 2	H319
	Acute Tox. 3	H331
	Muta 2	H341
	STOT SE 1	H370
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		

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2.2.	Label elements	
	Product identification:	BIOFIX
	Identification number:	-
	Authorisation number:	-
	Hazard pictograms:	 GHS02  GHS06  GHS07  GHS08
	Signal word:	Danger
	Hazard statements:	H225 Highly flammable liquid and vapor. H315 Causes skin irritation. H319 Causes serious eye irritation. H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled. H341 Suspected of causing genetic defects. H370 Causes damage to organs by inhaling, by skin contact and by swallowing.
	Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/face protection. 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+P311 IF exposed or concerned: Call a POISON CENTER or doctor.
	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)
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67-56-1/ 200-659-6/ 603-001-00-X	-	≥ 50	methanol	Flam. liq. 2, H225 Acute tox. 3, H331 Acute tox. 3, H311 Acute tox. 3, H301 STOT-SE 1, H370
50-00-0/ 200-001-8/ 605-001-00-5	-	≤ 10	formaldehyde, 37%	Acute tox. 3; H301 Acute tox. 3; H311 Skin corr. 1B; H314 Skin sens. 1; H317 Acute tox. 3; H331 Muta. 2; H341 Carc. 1B; H350
64-19-7/ 200-580-7/ 607-002-00-6	-	≤ 5	acetic acid, 99%	Flam. Liq. 3; H226 Skin corr. 1A; H314

SECTION 4. First aid measures		
4.1.	Description of first aid measures	
	General notes:	-
	Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration. Rush the afflicted person to the hospital while keeping them in lateral recumbent position in order to keep the airways clear.
	Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse with water and expectorate. Make the afflicted person drink 1 - 2 glasses of water (200 - 400 ml). The afflicted person should drink one glass (100 ml) of 40% ethanol (adult dose). Place the afflicted person in the half lying position and rush them to hospital while constantly calming them down. If the afflicted person is vomiting, there may be risk of pulmonary aspiration.
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Airways irritation and possible lung damage due to high levels of vapor concentration. Absorption may cause toxic effects.
	Following skin contact:	Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.
	Following eye contact:	Mild to moderate irritation due to vapor, conjunctivitis, later chemosis, lesser possibility of cornea damage. Visual impairments may occur later, after the absorption.
	Following ingestion:	Stomach and bowel irritation, feeling unwell, vomiting, strong abdominal pain. Absorption may cause toxic effects.

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

SECTION 5. Firefighting measures					
5.1.	Extinguishing media				
	<table> <tr> <td>Suitable extinguishing media:</td><td>Small fire - water spray, dry powder, CO₂ Large fire - water spray or alcohol-resistant foam</td></tr> <tr> <td>Unsuitable extinguishing media:</td><td>water jet</td></tr> </table>	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam	Unsuitable extinguishing media:	water jet
Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam				
Unsuitable extinguishing media:	water jet				
5.2.	Special hazards arising from the substance or mixture				
	<table> <tr> <td>Hazardous byproducts of fire:</td><td>No information available</td></tr> </table>	Hazardous byproducts of fire:	No information available		
Hazardous byproducts of fire:	No information available				
5.3.	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray, in order to prevent explosion.				
5.4.	Additional information				
	Remove sources of heat and ignition. 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						
	<table> <tr> <td>Protective equipment:</td><td>Use personal protective equipment (see Section 8).</td></tr> <tr> <td>Accident prevention methods:</td><td>Evacuate members of all non-essential personnel and those members without protective equipment. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.</td></tr> <tr> <td>Emergency procedures:</td><td>Mark the area using proper signs.</td></tr> </table>	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. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.	Emergency procedures:	Mark the area using proper signs.
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. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. 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 materials for containment and cleaning up						
6.3.1.	<table> <tr> <td>Bunding, covering of drains; capping procedures:</td><td>Sand or clay barriers.</td></tr> </table>	Bunding, covering of drains; capping procedures:	Sand or clay barriers.				
Bunding, covering of drains; capping procedures:	Sand or clay barriers.						

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

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures for fire prevention:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition. Carry out measures for preventing static electricity.
	Measures for preventing spray and dust formation:	Secure proper ventilation.
	Environmental precautions:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3.	Specific end use(s)	
	Recommendations:	-

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Industrial sector specific solutions:	-
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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	
Methanol	67-56-1	200	260	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*), end-of-shift urinary excretion
Formaldehyde	50-00-0	2	2.5	-
Acetic acid	64-19-7	10	25	-

* For all results pertaining creatinine levels, creatinine concentration < 0.5 g/l and > 3.0 g/l may not be taken into consideration

Substance: -

EC No: - CAS No: -

DNEL

Industrial

Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
Oral	-	-	-	-
Inhalation	1 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)	260 mg/m ³ (methanol)	0.5 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)	9 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)
Dermal	-	40 mg/kg (methanol)	0.037 mg/cm ² (formaldehyde)	240 mg/kg (formaldehyde) 40 mg/kg (methanol)

Critical physical parameters: solubility, flammability, corrosivity:

-

Consumer

Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
Oral	-	8 mg/kg (methanol)	-	4.1 mg/kg (formaldehyde) 8 mg/kg (methanol)
Inhalation	50 mg/m ³ (methanol)	50 mg/m ³ (methanol)	0.1 mg/m ³ (formaldehyde) 50 mg/m ³ (methanol)	3.2 mg/m ³ (formaldehyde) 50 mg/m ³ (methanol)

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Dermal	-	8 mg/kg (methanol)	0.012 mg/cm ² (formaldehyde)	120 mg/kg (formaldehyde) 8 mg/kg (methanol)
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PNEC

Environmental protection target	PNEC
Fresh water	0.47 mg/l (formaldehyde) 154 mg/l (methanol)
Freshwater sediments	2.44 mg/kg (formaldehyde) 570.4 mg/kg (methanol)
Marine water	0.47 mg/l (formaldehyde) 15.4 mg/l (methanol)
Marine sediments	2.44 mg/kg (formaldehyde)
Food chain	No information available
Microorganisms in sewage treatment	0.19 mg/l (formaldehyde) 100 mg/l (methanol)
Soil (agricultural)	0.21 mg/kg (formaldehyde) 23.5 mg/kg (methanol)
Air	No information available

8.2. Exposure controls

8.2.1. Appropriate engineering measures

Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
Structural measures to prevent exposure:	No information available
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection:	Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).
8.2.2.2. Skin protection:	

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	Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN374. Full contact: Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min Splash contact: Gloves material: polychloroprene Glove thickness: 0.65 mm Time until perforation: >240 min
	Other skin protection:	Complete suit protecting against chemicals (EN 340) The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Use mask that covers the entire face (EN 136). Recommended filter type: ABEK (EN 143). Use respirators and components tested according to and approved by the standard (EU).
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	No information available
	Colour:	colorless	No information available
	Odour:	methanol	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:	65 °C	No information available
	Flash point:	15 °C	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:	lower: 5.5 % (V) (methanol) upper: 44 % (V) (methanol)	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:	With halogen elements, oxidizing substances, reducing agents, acids.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Halogen elements, oxidizing substances, reducing agents, acids.
10.6.	Hazardous decomposition products:	Irritating vapors and gases.

SECTION 11. Toxicological information					
11.1.	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	LD ₅₀	-	5630 mg/kg (methanol)

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Dermal:	No information available	rabbit	LD ₅₀	-	17.100 mg/kg
Inhalation:	No information available	rat	LC ₅₀	4 h	131.25 mg/l

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: Irritating to respiratory system.

Irritation and corrosion

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

Sensitization

Skin sensitization:	Does not cause sensitization.
Respiratory sensitization:	No information available

Symptoms related to the physical, chemical and toxicological characteristics:

Oral exposure:	Stomach and bowel irritation, feeling unwell, vomiting, strong abdominal pain. Absorption may cause toxic effects.
Dermal exposure:	Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.
Inhalation exposure:	Airways irritation and possible lung damage due to high levels of vapor concentration. Absorption may cause toxic effects.
Eye exposure:	Mild to moderate irritation due to vapor, conjunctivitis, later chemosis, lesser possibility of cornea damage. Visual impairments may occur later, after the absorption.

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	-

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 mice and rats did not indicate carcinogenic effects.

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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.
Germ cell mutagenicity :	No information available
Reproductive toxicity:	No toxicity on reproductive organs was determined in low concentrations.

Summary of evaluation of the CMR properties; :	Current studies indicate that low methanol concentrations do not cause CMR effects. Further detailed tests are required.
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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	<i>Lepomis macrochirus</i> (Bluegill sunfish)	No information available	No information available	15.400 mg/l (methanol)
Crustacea:	EC ₅₀	48 hours	<i>Daphnia magna</i>	No information available	No information available	>10.0000 mg/l (methanol)
Algae/aquatic plants:	IC ₅₀	8 days	<i>Pseudokirchneriella subcapitata</i> (green algae)	No information available	No information available	22.000 mg/l (methanol)
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-

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Crustacea:	EC ₅₀	48 hours	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
99%	30 days	No information available	No information available	readily biodegradable (methanol)

12.3. Bioaccumulative potential

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

Value	Concentration	pH	°C	Method	Evaluation	Note
- 0.77 (methanol)	No information available	-	-	experimental	No information available	bioaccumulation is not expected

Bioconcentration Factor (BCF)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

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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 (Daphnia)	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				
	Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex III or a PBT/vPvB assessment was not conducted.				

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:
	Waste material must be disposed of according to the national and local rules and regulations. Do not mix with other sorts of waste. Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste codes/waste designations according to Low:
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.4.	Sewage disposal – relevant information:
	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:
	Directive 2009/98/EC on waste and repealing certain directives.

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol solution)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol solution)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-

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Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol solution)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol solution)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol solution)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmental hazards:	-
Special precautions for user:	-
Further information:	
-	

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

Trade name:	BIOFIX				
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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 of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on 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.	<table> <tr> <td>Abbreviations and acronyms:</td><td> PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity – single exposure IMDG International Maritime Dangerous Goods IATA International Air Transport Association GHS Globally Harmonized System of Classification and Labelling of Chemicals </td></tr> </table>	Abbreviations and acronyms:	PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity – single exposure IMDG International Maritime Dangerous Goods IATA International Air Transport Association GHS Globally Harmonized System of Classification and Labelling of Chemicals		
Abbreviations and acronyms:	PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity – single exposure IMDG International Maritime Dangerous Goods IATA International Air Transport Association GHS Globally Harmonized System of Classification and Labelling of Chemicals				
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)				
<table> <tr> <td>Classification</td><td>Classification procedure</td></tr> <tr> <td>-</td><td>-</td></tr> </table>		Classification	Classification procedure	-	-
Classification	Classification procedure				
-	-				

Trade name:	BIOFIX				
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16.5.	Relevant H statements (number and full text)	
	H: 225	Highly flammable liquid and vapor.
	226	Flammable liquid and vapor.
	301+311+331	Toxic if swallowed, in contact with skin or if inhaled.
	314	Causes severe skin burns and eye damage.
	315	Causes skin irritation.
	317	May cause an allergic skin reaction.
	319	Causes serious eye irritation.
	341	Suspected of causing genetic defects.
	350	May cause cancer.
	370	Causes damage to organs if inhaled, if it comes into contact with skin, and if swallowed.
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment
-

Trading name:	HISTANOL 100				
Product code:	H100-X**	Revision date:	13 May 2019	Version:	

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	HISTANOL 100
	Chemical name:	Ethyl alcohol
	Catalogue number:	H100-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in histocytology and cytology sample processing.
	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*:
	Flam. Liq. 2	H225
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	HISTANOL 100
	Identification number:	-
	Authorization number:	-

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Hazard pictograms:	
	GHS02
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
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)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- xxxx	≤ 100%	ethanol	Flam. Liq. 2; H225

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.

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	Following ingestion:	Rinse the mouth thoroughly with 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:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Formation of toxic gases is possible during heating or in case of fire.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. 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. Keep away from ignition sources.

Trading name:	HISTANOL 100			
Product code:	H100-X**	Revision date:	13 May 2019	Version:

	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 protective barrier or barriers made of similar materials.
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:	Secure proper ventilation. 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. Do not use tools that cause sparks. Do not smoke.
	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:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.

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	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 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	
Ethanol	64-17-5	1000/-	1900/-	-
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	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)
PNEC				

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Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	0.63 mg/kg (ethanol)
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:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.

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8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
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	No information available
	Colour:	colourless	No information available
	Odour:	alcohol like	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	-114.5°C	No information available
	Initial boiling point and boiling range:	78 °C	No information available
	Flash point:	13 °C	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:	lower: 3.5 Vol % upper: 15 Vol %	No information available
	Vapour pressure:	59 hPa	No information available
	Vapour density:	No information available	No information available
	Relative density:	0.711 – 0.87778 (20°C)	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	1 g/l (20°C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	Product is not selfigniting	No information available

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	Decomposition temperature:	No information available	No information available
	Viscosity:	1.2 mPas (dynamic at 20°C)	No information available
	Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	Ignition temperature: 425 °C		

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:	Avoid heat, sparks, open flames and other ignition sources.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

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:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	-	-	-	-
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	20.000 mg/l
	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				

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

Sensitization

Skin sensitization:	No information available.
Respiratory sensitization:	No information available.

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	-
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	-

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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:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
	Genotoxicity:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
	Reproductive toxicity:	Based on available data, the classification criteria are not met.

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	Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
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11.2	Practical experiences:
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	Classification observations:	No information available
	Other observations:	No information available

11.3	General notes:
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Trading name:	HISTANOL 100				
Product code:	H100-X**	Revision date:	13 May 2019	Version:	

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	4 days	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC 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

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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 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	-

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	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
	Not applicable.

12.6	Other adverse effects
	No further relevant information available.

SECTION 13. Disposal considerations

13.1	Waste treatment methods
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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

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.

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13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Inland waterway transport (ADN)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
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:	1170

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UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
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; 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:	-

Trading name:	HISTANOL 100			
Product code:	H100-X**	Revision date:	13 May 2019	Version:

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:	Manufacturer's MSDS file.	
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:	H225	Highly flammable liquid and vapor.
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:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	HISTANOL 95
	Chemical name:	Ethyl alcohol
	Catalogue number:	H95-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in histocytology and cytology sample processing.
	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*:
	Flam. Liq. 2	H225
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	HISTANOL 95
	Identification number:	-
	Authorization number:	-

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

Hazard pictograms:	
	GHS02
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
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)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- xxxx	~ 95%	ethanol	Flam. Liq. 2; H225

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.

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

	Following ingestion:	Rinse the mouth thoroughly with 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:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Formation of toxic gases is possible during heating or in case of fire.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. 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. Keep away from ignition sources.

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

	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.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.
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:	Secure proper ventilation. 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. Do not use tools that cause sparks. Do not smoke.
	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:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 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	
Ethanol	64-17-5	1000/-	1900/-	-
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	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)
PNEC				

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	0.63 mg/kg (ethanol)
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:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
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	No information available
	Colour:	colourless	No information available
	Odour:	alcohol like	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	-114.5°C	No information available
	Initial boiling point and boiling range:	78 °C	No information available
	Flash point:	13 °C	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:	lower: 3.5 Vol % upper: 15 Vol %	No information available
	Vapour pressure:	59 hPa	No information available
	Vapour density:	No information available	No information available
	Relative density:	0.711 – 0.87778 (20°C)	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	1 g/l (20°C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

	Auto-ignition temperature:	Product is not selfigniting	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	1.2 mPas (dynamic at 20°C)	No information available
	Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	Ignition temperature: 425 °C		

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:	Avoid heat, sparks, open flames and other ignition sources.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

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:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	-	-	-	-
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	20.000 mg/l
	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.		

Trading name:	HISTANOL 95				
Product code:	H95-X**	Revision date:	13 May 2019	Version:	

	Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note	
Skin corrosion/irritation:	-	-	-	-	-	
Serious eye damage/irritation	-	-	-	-	-	
	Sensitization					
Skin sensitization:		No information available.				
Respiratory sensitization:		No information available.				
	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	-
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	-

Trading name:	HISTANOL 95				
Product code:	H95-X**	Revision date:	13 May 2019	Version:	

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:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
	Genotoxicity:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
	Reproductive toxicity:	Based on available data, the classification criteria are not met.

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	Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
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11.2	Practical experiences:
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	Classification observations:	No information available
	Other observations:	No information available

11.3	General notes:
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Trading name:	HISTANOL 95				
Product code:	H95-X**	Revision date:	13 May 2019	Version:	

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	4 days	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC 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

Trading name:	HISTANOL 95				
Product code:	H95-X**	Revision date:	13 May 2019	Version:	

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 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	-

Trading name:	HISTANOL 95				
Product code:	H95-X**	Revision date:	13 May 2019	Version:	

	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
	Not applicable.

12.6	Other adverse effects
	No further relevant information available.

SECTION 13. Disposal considerations

13.1	Waste treatment methods
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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

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.

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Inland waterway transport (ADN)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
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:	1170

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
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; 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:	-

Trading name:	HISTANOL 95			
Product code:	H95-X**	Revision date:	13 May 2019	Version:

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:		Manufacturer's MSDS file.	
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:	H225	Highly flammable liquid and vapor.	
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:	HEMATOXYLIN G2				
Product code:	HEMG2-OT-X**	Revision date:	15 May 2019	Version:	5

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1.	Product identifier	
	Trading name:	HEMATOXYLIN G2
	Chemical name:	-
	Catalogue number:	HEMG2-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Hematoxylin according to Gill for nuclear staining.
	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
	Fax no.:	+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 INFORMATION		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification (REGULATION (EC) No. 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Acute Tox. 4	H302
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Classification according to EC Directive Nr. 1272/2008 CLP)	
	Product identification:	HEMATOXYLIN G2
	Identification number:	-
	Authorization no.:	-

Trading name:	HEMATOXYLIN G2				
Product code:	HEMG2-OT-X**	Revision date:	15 May 2019	Version:	5

Hazard pictograms:	 GHS07				
Signal word:	Warning				
Hazard statements:	H302 Harmful if swallowed.				
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.				
Further information:	-				
2.3.	Other hazards				
	-				

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
107-21-1/ 203-473-3/ 603-027-00-1	01-2119456816- 28-xxxx	≥ 25	ethylene glycol	Acute Tox. 4, H302

SECTION 4 FIRST AID MEASURES

4.1.	Description of first aid measures			
	General notes:	-		
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.		
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.		
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.		
	Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.		
	Self-protection of the first aider:	Treat symptomatically.		

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4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.
	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

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

SECTION 6 ACCIDENTAL RELEASE MEASURES		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Wear protective equipment (see Section 8).	

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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 inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	-	

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

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	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

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	
Ethylene glycol	107-21-1	20/40	52/104	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	-	-	35 mg/ kg (ethylene glycol)	-
Dermal	-	-	-	106 mg/kg (ethylene glycol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	7 mg/kg (ethylene glycol)	-
Dermal	-	-	-	53 mg/kg (ethylene glycol)
PNEC				
Environmental protection target		PNEC		

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Fresh water	10 mg/l (ethylene glycol)
Freshwater sediments	37 mg/kg (ethylene glycol)
Marine water	1 mg/l (ethylene glycol)
Marine sediments	3.7 mg/kg (ethylene glycol)
Food chain	No information available
Microorganisms in sewage treatment	199.5 mg/l (ethylene glycol)
Soil (agricultural)	1.53 mg/kg (ethylene glycol)
Air	No information available

8.2.	Exposure controls	
8.2.1.	Engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
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.

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	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	No information available
	Color:	red	No information available
	Odor:	very mild vinegar odour	No information available
	Odor threshold:	No information available	No information available
	pH:	2.0 - 2.5	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
	Vapor pressure:	No information available	No information available
	Vapor 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):	Soluble in water (20 °C)	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.

Trading name:	HEMATOXYLIN G2				
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10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	With strong oxidants, sodium-hydroxide, sulfuric acid, aluminum.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Aluminum.
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	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	rat	LD ₅₀	-	7.712 mg/kg (ethylene glycol)
Dermal exposure:	No information available	rabbit	LD ₅₀	-	>3.500mg/kg (ethylene glycol)
Inhalation exposure:	No information available	-	LC ₅₀	-	-

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

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

Respiratory irritation:

No information available

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	rabbit	-	-	Slight irritation (ethylene glycol)
Eye irritation:	24 h	rabbit	-	-	Slight irritation (ethylene glycol)

Sensitization

Dermal exposure:	No information available
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Inhalation exposure:	No information available
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Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.
Dermal exposure:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.
Inhalation exposure:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
Eye exposure:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-

Trading name:	HEMATOXYLIN G2				
Product code:	HEMG2-OT-X**	Revision date:	15 May 2019	Version:	5

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:	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.
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:	-
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11.2.	Practical experiences:
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	Remarks relevant for classification:	No information available
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	Other remarks:	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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Trading name:	HEMATOXYLIN G2				
Product code:	HEMG2-OT-X**	Revision date:	15 May 2019	Version:	5

Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Fish	No information available	72.860 mg/l (ethylene glycol)	-
Crustacea:	EC ₅₀	48 hours	water flea	No information available	>100 mg/l (ethylene glycol)	-
Algae/aquatic plants	IC ₅₀	8 days	algae	No information available	6.500-13.000 mg/l (ethylene glycol)	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-

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

12.2. Persistence and degradability

Abiotic degradation

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

Biodegradation

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

Trading name:	HEMATOXYLIN G2				
Product code:	HEMG2-OT-X**	Revision date:	15 May 2019	Version:	5

12.3.	Bioaccumulative potential					
	Partition coefficient: n-octanol/water (log Kow):					
	Value	Concentration	pH	°C	Method	Evaluation
	-	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
	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
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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:	HEMATOXYLIN G2				
Product code:	HEMG2-OT-X**	Revision date:	15 May 2019	Version:	5

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:	-
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:	-

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Product code:	HEMG2-OT-X**	Revision date:	15 May 2019	Version:	5

Further information:	The product is not subject to classification.
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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:	-
	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. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity - single exposure

Trading name:	HEMATOXYLIN G2				
Product code:	HEMG2-OT-X**	Revision date:	15 May 2019	Version:	5

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.
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:	EOSIN Y 2% ALCOHOLIC				
Product code:	EOYA-20-OT-X**	Date of compilation:	20 May 2019	Version:	1

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	EOSIN Y 2% ALCOHOLIC
	Chemical name:	-
	Catalogue number:	EOYA-20-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Reagent for cytoplasm counterstaining.
	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*:
	Flam. Liq. 2	H225
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	EOSIN Y 2% ALCOHOLIC
	Identification number:	-
	Authorization number:	-

Trading name:	EOSIN Y 2% ALCOHOLIC				
Product code:	EOYA-20-OT-X**	Date of compilation:	20 May 2019	Version:	1

Hazard pictograms:		GHS02
Signal word:	Danger	
Hazard statements:	H225 Highly flammable liquid and vapor.	
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.	
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)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- xxxx	≥ 50%	ethanol	Flam. Liq. 2; H225
64-19-7/ 200-580-7/ 607-002-00-6	-	< 0.5%	acetic acid	Flam. Liq. 3; H226 Skin Corr. 1A; H314

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.

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	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 mouth thoroughly with 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:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Formation of toxic gases is possible during heating or in case of fire.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. 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. Keep away from ignition sources.
	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.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.
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:	Secure proper ventilation. 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. Do not use tools that cause sparks. Do not smoke.
	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:	Protect against electrostatic charges.
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	

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	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 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	
Ethanol	64-17-5	1000/-	1900/-	-
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	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-

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Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)

PNEC	
Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	0.63 mg/kg (ethanol)
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:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min

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	Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
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	No information available
	Colour:	orange to pink-red	No information available
	Odour:	ethanol like	No information available
	Odor threshold:	No information available	No information available
	pH:	5.4 -5.7	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:	21 °C	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

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	Solubility(ies):	1 g/l (20°C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	Product is not selfigniting	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	1.2 mPas (dynamic at 20°C)	No information available
	Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.	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:	Avoid heat, sparks, open flames and other ignition sources.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

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:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	-	-	-	-
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	20.000 mg/l
	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	-	

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Aspiration hazard:		No information available.				
Irritation and corrosion						
Exposure time		Species	Evaluation	Method	Note	
Skin corrosion/irritation:	-	-	-	-	-	
Serious eye damage/irritation	-	-	-	-	-	
Sensitization						
Skin sensitization:		No information available.				
Respiratory sensitization:		No information available.				
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	-
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	-

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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):						
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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	-

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
Carcinogenicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
Genotoxicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.

Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
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11.2	Practical experiences:
	Classification observations:
	Other observations:
11.3	General notes:

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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	4 days	No information available	No information available	No information available	-
Other organisms		-	-	-	-	-	-
Chronic (long-term) toxicity		Dose	Exposure time	Species	Method	Evaluation	Note
Fish		LC 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		-

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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 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

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	No information available	No information available	No information available	No information available	-

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

12.5	Results of PBT and vPvB assessment				
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	Not applicable.				
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12.6	Other adverse effects				
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	No further relevant 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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	15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances				
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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:
	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:
	Disposal must be made according to official regulations.

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Inland waterway transport (ADN)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
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; 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	

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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:		Manufacturer's MSDS file.
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:	H225 H226 H314	Highly flammable liquid and vapor. Flammable liquid and vapor. Causes severe skin burns and eye damage.
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:	BLUING REAGENT			
Product code:	BR-OT-X**	Date of compilation:	04 June 2019	Version: 4

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1.	Product identifier	
	Trading name:	BLUING REAGENT
	Chemical name:	-
	Catalogue number:	BR-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Reagent for conversion of red hematoxylin-stained nuclei to blue.
	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
	Fax no.:	+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 INFORMATION		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification (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.	Classification according to EC Directive Nr. 1272/2008 CLP)	
	Product identification:	BLUING REAGENT
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	-
	Signal word:	-

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Product code:	BR-OT-X**	Date of compilation:	04 June 2019	Version: 4

	Hazard statements:	-
	Precautionary statements:	-
	Further information:	-
2.3.	Other hazards	
	-	

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
-	-	-	Contains no hazardous substances	-

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

Trading name:	BLUING REAGENT				
Product code:	BR-OT-X**	Date of compilation:	04 June 2019	Version:	4

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

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

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

Trading name:	BLUING REAGENT			
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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	-	

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

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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	
-	-	-	-	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	-	-	-	-
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			

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8.2.1.	Engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
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	No information available
	Color:	colourless	No information available

Trading name:	BLUING REAGENT			
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Odor:	no odor	No information available
Odor threshold:	No information available	No information available
pH:	>8.0	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
Vapor pressure:	No information available	No information available
Vapor 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):	Soluble in water (20 °C)	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.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
10.6.	Hazardous decomposition products:	No information available.

SECTION 11 TOXICOLOGICAL INFORMATION	
11.1.	Information on toxicological effects
	Acute toxicity:

Trading name:	BLUING REAGENT				
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Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-

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

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

Respiratory irritation: No information available

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	rabbit	-	-	-
Eye irritation:	-	rabbit	-	-	-

Sensitization

Dermal exposure:	No information available
Inhalation exposure:	No information available

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Swallowing may cause discomfort in abdomen and abdominal pains.
Dermal exposure:	Allergic persons may display irritation.
Inhalation exposure:	Allergic persons may display irritation after prolonged or repeated exposure.
Eye exposure:	May cause irritation.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
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Trading name:	BLUING REAGENT					
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Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

Specific 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)

Trading name:	BLUING REAGENT					
Product code:	BR-OT-X**	Date of compilation:	04 June 2019	Version:	4	

	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.
	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:	-
11.2.	Practical experiences:	
	Remarks relevant for classification:	No information available
	Other remarks:	No information available
11.3.	General notes:	
	-	

SECTION 12 ECOLOGICAL INFORMATION:						
12.1.	Toxicity					
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-

Trading name:	BLUING REAGENT					
Product code:	BR-OT-X**	Date of compilation:	04 June 2019	Version:	4	

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	No information available

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (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	No information	No information	No information available	-

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		available	available	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

13.1.1. Product/Packaging disposal:

Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
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Trading name:	BLUING REAGENT			
Product code:	BR-OT-X**	Date of compilation:	04 June 2019	Version: 4

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.
UN proper shipping name:	-
Transport hazard class(es):	-

Trading name:	BLUING REAGENT			
Product code:	BR-OT-X**	Date of compilation:	04 June 2019	Version: 4

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

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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%
			STOT-SE	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	
-	

Trade name:	BIOMOUNT NEW LOW				
Product code:	BMNL-X**	Date of compilation:	04 June 2019	Version:	3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	BIOMOUNT NEW LOW
	Chemical name:	-
	Catalogue number:	BMNL-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For covering microscope sections and mounting covering glasses.
	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 numbers	
	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:	Warning statements*:
	Aspir. Tox. 1	H304
2.1.2.	Additional information	
	EUH066	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	BIOMOUNT NEW LOW
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	
	GHS08
Signal word:	Danger
Hazard statement:	H304 May be fatal if swallowed and enters airways. EUH066 Repeated exposure may cause skin dryness or cracking.
Precautionary statements:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P331 Do NOT induce vomiting. P403+P235 Store in a well-ventilated place. Keep cool.
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)
-/ 920-901-0/ -	01-2119456810-40	60-80%	Hydrocarbons, C11- C13, isoalkanes, <2% aromatics	Aspir. tox. 1; H304 EUH066

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. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation.
Following skin contact:	Remove contaminated clothing. Thoroughly wash with water and soap for 15 minutes.

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	Following eye contact:	Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open. Contact a physician if irritation occurs.
	Following ingestion:	DO NOT induce vomiting. Seek immediate medical attention.
	Self-protection of the first aider	-

4.2. Most important symptoms and effects, both acute and delayed

	Following inhalation:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.
	Following skin contact:	Prolonged and/or repeated exposure to low viscosity content may cause skin dryness or cracking. May be irritating to the eyes, nose, throat and lungs.
	Following eye contact:	Eye irritation may occur during exposure to vapor concentrations above recommended level.
	Following ingestion:	If swallowing occurs, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.

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

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SECTION 5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:	Water spray, foam, dry powder, CO ₂
Unsuitable extinguishing media:	Straight streams of water

5.2. Special hazards arising from the substance or mixture

Hazardous by products of fire:	Smoke, fume, incomplete combustion products, carbon oxides.
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5.3. Advice for firefighters

Evacuate the area. Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing). Use water spray to cool fire exposed surfaces and to protect personnel.

5.4. Additional information

-

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment:	When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus.
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Trade name:	BIOMOUNT NEW LOW				
Product code:	BMNL-X**	Date of compilation:	04 June 2019	Version:	3

	Accident prevention methods:	Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks.
	Emergency procedures:	Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection.
6.1.2.	For emergency responders:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112).
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use tools that cause sparks.
	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. Avoid skin contact.	
7.2.	Conditions for safe storage, including any incompatibilities	

Trade name:	BIOMOUNT NEW LOW				
Product code:	BMNL-X**	Date of compilation:	04 June 2019	Version:	3

	Technical measures and storage conditions:	Keep in a cool and well-ventilated place. Keep away from heat and direct solar radiation.
	Packaging materials:	Teflon, polypropylene, stainless steel, carbon steel.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed. Store in a cool, well-ventilated area.
	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:	Suitable materials and coating are teflon, polypropylene, polyethylene, stainless steel, carbon steel. Unsuitable materials and coatings include ethylene propylene diene monomer (EPDM), natural rubber, polystyrene, butyl rubber.

7.3.	Specific end use(s)	
	Recommendations:	This product attracts static electricity that may cause electrical sparking (ignition source) that may ignite flammable vapors of the liquid. The liquid is usually an isolator if its conductivity level is under 100 pS/m. It is considered a semiconductor that attracts static electricity if its conductivity level is less than 10,000 pS/m. Regardless of the type of the liquid (isolator or semiconductor), precautions are the same. Numerous factors, such as the liquid temperature, contaminants, antistatic additives and filtration may severely influence the liquid conductivity.
	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	
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	-	171*	1200*	No information available
* Source - material safety data sheet provided by the raw materials supplier				
Substance:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:

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Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
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

Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment. Wash hands after handling the product and before eating and/or drinking.
Structural measures to prevent exposure:	Adequate ventilation should be provided so that exposure limits are not exceeded. Use explosion-proff ventilation equipment.
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	See Section 7.2

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	

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	Hand protection:	In case prolonged or repeated contact with the product, use nitril rubber protective gloves (EN 374).
	Other skin protection:	Wear full protective suit that protects from chemicals (EN 340) and shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values (or because of inadequate ventilation), use full gas mask (EN 136) equipped with a recommended filter type A.
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	No information available
	Colour:	colourless	No information available
	Odour:	faint	No information available
	Odour 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:	170 - 250 °C	No information available
	Flash point:	62 °C	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

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	Relative density	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	Negligible	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	> 200 °C	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:	No information available
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:	Hazardous polymerization will not occur.
10.4.	Conditions to avoid:	Open flames and high energy ignition sources.
10.5.	Incompatible materials:	Strong oxidants.
10.6.	Hazardous decomposition products:	Product decomposition will not occur at ambient temperature.

SECTION 11. Toxicological information					
11.1.	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	LD ₅₀ > 5000 mg/kg	-	-
Dermal:	No information available	rabbit	LD ₅₀ > 5000 mg/kg	-	-
Inhalation:	No information available	rat	LC ₅₀ > 5000 mg/kg	4 h	-
	Specific target organ toxicity - single exposure (STOT-SE):				
	Specific effects		Target organ	Note	
Oral:	No information available		No information available	-	

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

Aspiration hazard:	Insignificant danger at normal handling temperature.
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Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	No information available	rabbit	Not irritating.	OECD	-
Serious eye damage/irritation	No information available	rabbit	Not irritating.	not specified	-

Sensitization

Skin sensitization:	Not expected to be a skin sensitizer.
Respiratory sensitization:	Not expected to be a respiratory sensitizer.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	If swallowing occurs, aspiration of the vomit may also occur and cause chemical pneumonitis or pulmonary oedema.
Dermal exposure:	Prolonged and/or repeated exposure to low viscosity content may cause irritation and dermatitis, skin drying or cracking.
Inhalation exposure:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.
Eye exposure:	Eye irritation may occur during exposure to vapor concentrations above recommended level.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-

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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:	No carcinogenicity studies were made, but since the product is not mutagenic and causes a minimal level of toxicity, it can be assumed that chronic exposure will not cause tumors.
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

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	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	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	No information available	No information available	-	-
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	No information available
Crustacea:	EC ₅₀	48 hours	No information available	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	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
No information available	No information available	-	-	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	Not expected.

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Chronic toxicity on crustacea (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	Not expected.
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12.4. Mobility in soil

Known or predicted distribution in environmental compartments:					
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:

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	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection. 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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13.1.2.	Waste codes/waste designations according to Law:
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	European Waste Code: 08 XX XX These codes are assigned based upon the most common uses for this material and may not reflect contaminants resulting from actual use. Waste producers need to assess the actual process used when generating the waste and its contaminants in order to assign the proper waste disposal code(s).
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13.1.3.	Waste codes/waste designations according to Law:
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	Incinerating the product at high temperatures is recommended in order to avoid incomplete combustion products.
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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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	Empty Container Warning: Empty containers may contain residue and can be dangerous. Do not attempt to refill or clean containers without proper instructions. Empty drums should be completely drained and safely stored until appropriately reconditioned or disposed. Empty containers should be taken for recycling, recovery or disposal through suitably qualified or licensed contractor and in accordance with governmental regulations. Do not pressurise, cut, weld, braze, solder, drill, grind or expose such containers to heat, flame, sparks, static electricity or other sources of ignition. They may explode and cause injury or death.
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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.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

	Transporting/shipment by rail (RID)
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UN number:	Not subject to transport regulations.
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Trade name:	BIOMOUNT NEW LOW				
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UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
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:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 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:	-
Environmental hazards:	-
Special precautions for user:	-
Further information:	
-	

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

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	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 of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on 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. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT-SE 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: 304 (EUH066)	May be fatal if swallowed and enters airways. Repeated exposure may cause skin dryness or cracking.

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16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment		
-		