

KIT FOR RAPID HE STAINING OF FROZEN AND PARAFFIN- EMBEDDED SECTIONS

The kit contains:

BioClear New

BioFix

Histanol 100

Histanol 95

Deionized water

Hematoxylin G2

Bluing reagent

Eosin Y 2% alcoholic

BioMount New Low

Trade name:	BIOCLEAR NEW			
Product code:	BCN-X**	Date of compilation:	14 November 2022	Version: 7


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 used as clearing agent.
	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:	P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P331 Do NOT induce vomiting. P405 Store locked up. P501 Dispose of contents and container in accordance with local regulations.
Supplemental hazard information (EU):	-

2.3. Other hazards

Physical / Chemical Hazards:

Material can accumulate static charges which may cause an ignition. Material can release vapours that readily form flammable mixtures. Vapour accumulation could flash and/or explode if ignited. Combustible.

Health Hazards:

Repeated exposure may cause skin dryness or cracking. May be irritating to the eyes, nose, throat, and lungs.

Environmental Hazards:

No significant hazards. Material does not meet the criteria for PBT or vPvB in accordance with REACH Annex XIII.

Endocrine Disrupting Properties:

No known endocrine disrupting properties.

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.
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	Following inhalation:	Immediately remove from further exposure. Get immediate medical assistance. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. Give supplemental oxygen, if available. If breathing has stopped, assist ventilation with a mechanical device.
	Following skin contact:	Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse.
	Following eye contact:	Flush thoroughly with water. If irritation occurs, get medical assistance.
	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:	No important symptoms or effects.
	Following skin contact:	No important symptoms or effects.
	Following eye contact:	No important symptoms or effects.
	Following ingestion:	No important symptoms or effects.
4.3.	Indication of any immediate medical attention and special treatment needed	
	If ingested, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Use water fog, foam, dry chemical or carbon dioxide (CO ₂) to extinguish flames.
	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. Prevent run-off from fire control or dilution from entering streams, sewers or drinking water supply. Fire-fighters should use standard protective equipment and in enclosed spaces, self-contained breathing apparatus (SCBA). Use water spray to cool fire exposed surfaces and to protect personnel.	
5.4.	Additional information	
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SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	

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6.1.1.	For non-emergency personnel	
	Protective equipment:	See Section 8 for advice on the minimum requirements for personal protective equipment. Additional protective measures may be necessary, depending on the specific circumstances and/or the expert judgment of the emergency responders.
	Accident prevention methods:	Avoid contact with spilled material. Warn or evacuate occupants in surrounding and downwind areas if required, due to toxicity or flammability of the material. See Section 5 for fire fighting information.
	Emergency procedures:	See the Hazard Identification Section for Significant Hazards. See Section 4 for First Aid Advice.
6.1.2.	For emergency responders:	
	Respiratory protection: half-face or full-face respirator with filter(s) for organic vapor and, when applicable, H ₂ S, or self contained breathing apparatus (SCBA) can be used depending on the size of spill and potential level of exposure. If the exposure cannot be completely characterized or an oxygen deficient atmosphere is possible or anticipated, SCBA is recommended. Work gloves that are resistant to aromatic hydrocarbons are recommended. Note: gloves made of polyvinyl acetate (PVA) are not water-resistant and are not suitable for emergency use. Chemical goggles are recommended if splashes or contact with eyes is possible. Small spills: normal antistatic work clothes are usually adequate. Large spills: full body suit of chemical resistant, antistatic material is recommended.	
6.2.	Environmental precautions:	
	Large Spills: Dyke far ahead of liquid spill for later recovery and disposal. Prevent entry into waterways, sewers, basements or confined areas.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Land Spill: Stop leak if you can do so without risk. Water Spill: Stop leak if you can do so without risk. Confine the spill immediately with booms. Warn other shipping. Remove from the surface by skimming or with suitable absorbents. Seek the advice of a specialist before using dispersants.
6.3.2.	Cleaning up:	Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers. Recover by pumping or with suitable absorbent.
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
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7.1.1.	Protection measures	
	Measures to prevent fire:	Avoid contact with skin. Prevent small spills and leakage to avoid slip hazard. Material can accumulate static charges which may cause an electrical spark (ignition source).
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	When the material is handled in bulk, an electrical spark could ignite any flammable vapors from liquids or residues that may be present (e.g., during switch-loading operations). Use proper bonding and/or earthing procedures.
	Other measures:	This material is a static accumulator. A liquid is typically considered a nonconductive, static accumulator if its conductivity is below 100 pS/m (100x10E-12 Siemens per meter) and is considered a semiconductive, static accumulator if its conductivity is below 10,000 pS/m. Whether a liquid is nonconductive or semiconductive, the precautions are the same. A number of factors, for example liquid temperature, presence of contaminants, anti-static additives and filtration can greatly influence the conductivity of a liquid.
7.1.2.	Advice on general occupational hygiene:	
	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Discard contaminated clothing and footwear that cannot be cleaned. Practice good housekeeping.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in a cool and well-ventilated area.
	Packaging materials:	Teflon, polypropylene, stainless steel, carbon steel.
	Requirements for storage rooms and vessels:	The type of container used to store the material may affect static accumulation and dissipation. Keep container closed. Handle containers with care. Open slowly in order to control possible pressure release.
	Advices for storage equipment:	Storage containers should be earthed and bonded. Fixed storage containers, transfer containers and associated equipment should be earthed and bonded to prevent accumulation of static charge.
	Further information on storage conditions:	Suitable materials and coating are carbon steel, stainless steel, teflon, polyethylene, polypropylene. Unsuitable materials and coatings: butyl rubber, natural rubber, ethylene-propylene-diene monomer (EPDM), polystyrene

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7.3.	Specific end use(s)	
	Recommendations:	Section 1 informs about identified end-uses.
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection				
8.1.	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m³	
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:
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		

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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.	Appropriate engineering controls
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	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-proof 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:	If contact is likely, safety glasses with side shields are recommended.
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8.2.2.2.	Skin protection
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	Hand protection:	If prolonged or repeated contact is likely, chemical-resistant gloves are recommended. If contact with forearms is likely, wear gauntlet-style gloves. Nitrile, minimum 0.38 mm thickness or comparable protective barrier material with a high performance level for continuous contact use conditions, permeation breakthrough minimum 480 minutes in accordance with CEN standards EN 420 and EN 374.
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	Other skin protection:	If prolonged or repeated contact is likely, chemical, and oil resistant clothing is recommended.
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8.2.2.3.	Respiratory protection:	<p>If engineering controls do not maintain airborne contaminant concentrations at a level which is adequate to protect worker health, an approved respirator may be appropriate. Respirator selection, use, and maintenance must be in accordance with regulatory requirements, if applicable. Types of respirators to be considered for this material include:</p> <p>Half-face filter respirator Type A filter material, European Committee for Standardization (CEN) standards EN 136, 140 and 405 provide respirator masks and EN 149 and 143 provide filter recommendations.</p> <p>For high airborne concentrations, use an approved supplied-air respirator, operated in positive pressure mode. Supplied air respirators with an escape bottle may be appropriate when oxygen levels are inadequate, gas/vapour warning properties are poor, or if air purifying filter capacity/rating may be exceeded.</p>
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8.2.2.4.	Thermal hazards:	No information available.
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	Comply with applicable environmental regulations limiting discharge to air, water and soil. Protect the environment by applying appropriate control measures to prevent or limit emissions.
	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/odour threshold:	faint/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	188°C - 210 °C	ASTM D86
	Flammability:	Not technically feasible	No information available
	Lower and upper explosion limit:	lower: 0.6 upper: 6.0	Extrapolated
	Flash point:	68 °C	ASTM D-93
	Auto-ignition temperature:	222 °C	ASTM E659
	Decomposition temperature:	No information available	No information available
	pH:	Not technically feasible	No information available
	Kinematic viscosity:	1.3 cSt (1.3 mm ² /sec) at 40 °C 1.74 cSt (1.74 mm ² /sec) at 20 °C	Calculated
	Solubility:	Negligible	No information available
	Partition coefficient n-octanol/water (log value):	> 4	Estimated
	Vapour pressure:	0.04 kPa (0.3 mm Hg) at 20 °C	No information available
	Density and/or relative density	0.76 (at 15 °C) with respect to water	Calculated
	Relative vapour density:	5.7 at 101 kPa (Air=1)	Calculated
	Particle characteristics:	Median particle size	Not applicable

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9.2.	Other information		
	Evaporation rate:	0,04 (n-butyl acetate = 1)	Calculated
	Explosive properties:	None	No information available
	Oxidising properties:	None	No information available
	Density (at 15 °C):	760 kg/m ³	ISO 12185
	Pour Point:	< -114 °C	ASTM D5950
	Molecular Weight:	165 g/mol	Calculated
	Hygroscopic:	No	No information available
	Coefficient of Thermal Expansion:	0.00098 per Deg C	Calculated

SECTION 10.: Stability and reactivity

10.1.	Reactivity:	See sub-section below.
10.2.	Chemical stability:	The product is stable under normal conditions.
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 oxidisers.
10.6.	Hazardous decomposition products:	Material does not decompose at ambient temperatures.

SECTION 11. Toxicological information

11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	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	-	Minimally toxic.
Dermal:	No information available	rabbit	LD ₅₀ > 5000 mg/kg	-	Minimally toxic.
Inhalation:	No information available	rat	LC ₅₀ > 5000 mg/ m ³	8 h	Minimally toxic.
	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:	May be fatal if swallowed and enters airways relates to potential for aspiration, a non-quantifiable hazard determined by physico-chemical properties (i.e. viscosity) that can occur during ingestion and also if it is vomited following ingestion. A DNEL cannot be derived. Risks from the physicochemical hazards of substances can be controlled by implementing risk management measures. For substances classified as H304, the following measures need to be implemented to control the aspiration hazard. Do not ingest. If swallowed then seek immediate medical attention. Do NOT induce vomiting.
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Irritation and corrosion

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

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Sensitization

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

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Symptoms related to the physical, chemical and toxicological characteristics
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Oral exposure:	May be fatal if swallowed and enters airways.
Dermal exposure:	May dry the skin leading to discomfort and dermatitis.
Inhalation exposure:	Negligible hazard at ambient/normal handling temperatures.
Eye exposure:	May cause mild, short-lasting discomfort to eyes.

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Repeated dose toxicity (subacute, subchronic, chronic)
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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-

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Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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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	-

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Chronic inhalation		No information available	No information available	-
CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)				
	Carcinogenicity:	Not expected to cause cancer. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline 453.		
	Mutagenicity <i>in-vitro</i> :	No information available		
	Genotoxicity:	No information available		
	Mutagenicity <i>in-vivo</i> :	No information available		
	Germ cell mutagenicity:	Not expected to be a germ cell mutagen. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline 471 473 474 476 478 479.		
	Reproductive toxicity:	Not expected to be a reproductive toxicant. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline 413 414 415.		
	Summary of evaluation of the CMR properties:	No information available		
11.2.	Information on other hazards:			
11.2.1.	Endocrine disrupting properties:			
	No known endocrine disrupting properties that affect human health.			
11.2.2.	Other information:			
	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	Oncorhynchus mykiss	No information available	-	1000 mg/l
Crustacea:	EC ₅₀	48 hours	Daphnia magna	No information available	-	1000 mg/l

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Algae/aquatic plants:	IC ₅₀	72 hours	Pseudokirchneriella subcapitata	No information available	-	1000 mg/l
Other organisms:	-	-	-	-	-	-
Chronic (long-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:	-	21 day(s)	Daphnia magna	-	-	NOELR 1 mg/l

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
Percent Degraded 31.3 : similar material	28 day (s)	Ready Biodegradability (water)	No information available	Expected to be inherently biodegradable

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12.3. Bioaccumulative potential						
Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
> 4	No information available	-	-	Estimated	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.
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		Highly volatile, will partition rapidly to air. Not expected to partition to sediment and wastewater solids.

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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 available	information	No information available	No information available	-
Water-Air	No information available	No available	information	No information available	No information available	-
Soil-Air	No information available	No available	information	No information available	No information available	-

12.5.	Results of PBT and vPvB assessment
	Material does not meet the Reach Annex XIII criteria for PBT or vPvB.

12.6.	Endocrine disrupting properties
	No known endocrine disrupting properties that affect the environment.

12.7.	Other adverse effects
	No adverse effects are expected.

SECTION 13. Disposal considerations

13.1.	Waste treatment methods
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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. 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:
	The European Waste Catalogue (EWC) code is specific to the waste generating process and waste constituents. Determine the EWC according to the criteria provided in the European Waste Catalogue and the hazardous waste list established by Commission Decision 2000/532/EC, as amended.

13.1.3.	Waste treatment – relevant information:
	Disposal recommendations based on material as supplied. Disposal must be in accordance with current applicable laws and regulations, and material characteristics at time of disposal.

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13.1.4.	Sewage disposal – relevant information:
	Product is suitable for burning in an enclosed controlled burner for fuel value or disposal by supervised incineration at very high temperatures to prevent formation of undesirable combustion products.
13.1.5.	Other disposal recommendations:
	Empty Container Warning (where applicable): 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:
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SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
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:	-

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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: -
	Restrictions: -

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

SECTION 16. Other information

16.1.	Indication of changes:	<p>Composition: Component Table for REACH information was modified.</p> <p>Section 09 median particle size information was added.</p> <p>Section 09: Freezing Point °C(°F) information was deleted.</p> <p>Section 09: Melting Point °C (F) information was deleted.</p> <p>Section 11 EU Annex II Endocrine Disruptor Data information was added.</p> <p>Section 12 EU Annex II Endocrine Disruptor Data information was added.</p> <p>Section 2 EU Annex II Endocrine Disruptor Data information was added.</p> <p>Section 9 melting and freezing points information was added.</p>
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16.2.	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
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:	<p>** "X" in the product code marks different volumes (different packaging of the product)</p> <p>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.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment

-

Trade name:	BIOFIX				
Product code:	BF-X**	Date of compilation:	22 Dec 2022	Version:	5

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 Corr. 1B	H314
	Skin Sens. 1B	H317
	Acute Tox. 3	H331
	Muta 2	H341
	STOT SE 1	H370
2.1.2.	Additional information	

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Endocrine Disrupting Properties: No known endocrine disrupting properties Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.
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* For full text of Hazard- and EU Hazard-statements: see SECTION 16

2.2.	Label elements	
	Product identification:	BIOFIX
	Identification number:	-
	Authorisation number:	-
	Hazard pictograms:	<div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center;">  GHS02 </div> <div style="text-align: center;">  GHS06 </div> <div style="text-align: center;">  GHS05 </div> <div style="text-align: center;">  GHS08 </div> </div>
	Signal word:	Danger
	Hazard statements:	H225 Highly flammable liquid and vapor. H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H341 Suspected of causing genetic defects. H350 May cause cancer. H370 Causes damage to organs (eyes).
	Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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):	-

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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)
67-56-1/ 200-659-6/ 603-001-00-X	-	80 – 85 %	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	-	9 – 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	-	4 – 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	

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	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.
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:	No information available
5.2.	Special hazards arising from the substance or mixture	
	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	
	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:	

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

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	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection				
8.1.	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m³	
Methanol	67-56-1	200/-	260/-	-
Formaldehyde	50-00-0	0.3/0.6	0.37/0.74	-
Acetic acid	64-19-7	10/20	25/50	-
* 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:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	0.75 mg/m³ (formaldehyde) 260 mg/m³ (methanol)	260 mg/m³ (methanol)	0.375 mg/m³ (formaldehyde) 260 mg/m³ (methanol)	9 mg/m³ (formaldehyde) 260 mg/m³ (methanol)
Dermal	-	40 mg/kg (methanol)	0.037 mg/cm² (formaldehyde)	240 mg/kg (formaldehyde) 40 mg/kg (methanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				

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Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
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)
Dermal	-	8 mg/kg (methanol)	0.012 mg/cm ² (formaldehyde)	102 mg/kg (formaldehyde) 8 mg/kg (methanol)

PNEC

Environmental protection target	PNEC
Fresh water	0.44 mg/l (formaldehyde) 154 mg/l (methanol)
Freshwater sediments	2.3 mg/kg (formaldehyde) 570.4 mg/kg (methanol)
Marine water	0.44 mg/l (formaldehyde) 15.4 mg/l (methanol)
Marine sediments	2.3 mg/kg (formaldehyde)
Food chain	No information available
Microorganisms in sewage treatment	0.19 mg/l (formaldehyde) 100 mg/l (methanol)
Soil (agricultural)	0.2 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.

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	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:	
	Hand protection:	<p>The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN374.</p> <p>Full contact:</p> <p>Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min</p> <p>Splash contact:</p> <p>Gloves material: polychloroprene Glove thickness: 0.65 mm Time until perforation: >240 min</p>
	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

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Colour:	colorless	No information available
Odour/odour threshold:	methanol/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	lower: 6 % (V) methanol upper: 36.5 % (V) methanol	No information available
Flash point:	12 °C	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
pH:	No information available	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
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:

Trade name:	BIOFIX				
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Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	LD ₅₀	-	125.13 mg/kg (methanol)
Dermal:	No information available	rabbit	LD ₅₀	-	375.13 mg/kg (methanol)
Inhalation:	No information available	rat	LC ₅₀	4 h	3.88 mg/l (methanol)

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

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

Aspiration hazard: No information available

Irritation and corrosion

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

Sensitization

Skin sensitization:	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.

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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	-
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	-

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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:	Possible carcinogen.		
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> :	Evidence of genetic defects.		
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 but formaldehyde has local carcinogenic activity in experimental animals; there is evidence for a threshold effect for tumors involving cytotoxicity and regenerative cell proliferation as the mode of action. Further detailed tests are required.		
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11.2.	Information on other hazards:		
11.2.1.	Endocrine disrupting properties:		
	No known endocrine disrupting properties that affect human health.		
11.2.2.	Other information:		
	-		

SECTION 12. Ecological information						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	<i>Lepomis macrochirus</i> (Bluegill sunfish)	No information available	No information available	15.400 mg/l (methanol)

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Crustacea:	EC ₅₀	48 hours	<i>Daphnia magna</i>	No information available	No information available	> 18.260 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	-
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	-

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12.3. Bioaccumulative potential						
Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	-	No information available	-
Bioconcentration Factor (BCF)						
Value	Species		Method		Evaluation	Note
No information available	No information available		No information available		No information available	No information available
Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (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		-

Trade name:	BIOFIX				
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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
	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.	Endocrine disrupting properties
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7.	Other adverse effects
	No information available

SECTION 13. Disposal considerations

13.1.	Waste treatment methods
-------	-------------------------

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

13.1.2.	Waste codes/waste designations according to Law:
	No information available

13.1.3.	Waste codes/waste designations according to Low:
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Trade name:	BIOFIX				
Product code:	BF-X**	Date of compilation:	22 Dec 2022	Version:	5

	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:
	-

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:	-
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:	-

Trade name:	BIOFIX				
Product code:	BF-X**	Date of compilation:	22 Dec 2022	Version:	5

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:		<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)		
National legislation:		<p>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</p>
15.2.	Chemical safety assessment	
	None	

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

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16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		
		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.
	H:	317	May cause an allergic skin reaction.
		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:		<p>** "X" in the product code marks different volumes (different packaging of the product)</p> <p>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.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment

-

Trading name:	HISTANOL 100				
Product code:	H100-X**	Revision date:	05 Dec 2022	Version:	6


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. Unsuitable for human consumption.
	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:	-

Trading name:	HISTANOL 100				
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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, hot sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P403+P235 Store in a well-ventilated place. Keep cool.
Supplemental hazard information (EU):	-
2.3	Other hazards
	<p>The product has no other known specific hazards for human or environment.</p> <p>Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.</p> <p>Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.</p>

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- 0147	min. 99 %	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:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.
Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.

Trading name:	HISTANOL 100				
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	Following eye contact:	In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 10 minutes). If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Place the victim in a comfortable position. Rinse the mouth with clean water. If the victim is conscious induce vomiting. Do not give the victim anything orally, and do not induce vomiting if the victim is unconscious or suffers from convulsions.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.
	Following eye contact:	May irritate the eyes.
	Following ingestion:	Ingestion of larger quantities may affect the central nervous system.
4.3	Indication of any immediate medical attention and special treatment needed	
	If larger quantities have entered the body, obtain medical treatment (gastric lavage, activated carbon).	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Extinguishing powder, alcohol-resistant foam, water, carbon-dioxide.
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Highly flammable liquid and vapour. In case of fire, smoke, and other combustion products (carbon monoxide, carbon dioxide) may be formed, the inhalation of such combustion products can have serious adverse effects on health. Vapours may form an explosive mix with air. Vapours may be ignited by open flames, sparks, electrical equipment, or static charge. Vapours may travel to great distances, ignite in contact with ignition sources and flash back to the primer source (container). Vapours of ethyl alcohol mix greatly with air and may form an explosive mixture. Air containing 3.3 – 19 % ethyl alcohol vapours may explode in contact with ignition sources. Diluting the mixture with large amounts of water results in the loss of its flammability (around 10 % concentration of ethyl alcohol).
5.3	Advice for firefighters	
	Wear full protective clothing and self-contained breathing apparatus. Cool the fire affected containers with water spray. Use water spray to dissipate alcohol vapours.	
5.4	Additional information	
	-	

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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.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.	
6.2	Environmental precautions:	
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.	
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:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).
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

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	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use non-sparkling tools and equipment.
	Measures to prevent aerosol and dust generation:	Ensure adequate 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:	Store in a well-ventilated place, protected from sunlight, away from sources of heat and ignition, in its original, unopened and hermetically sealed packaging, away from oxidizing agents, food, feed and articles of consumption.
	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:	-			

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EC No:	-	CAS No:	-	
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DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	1900 mg/m ³ (ethanol)	-	-	380 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	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m ³ (ethanol)	-	-	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	2.9 mg/kg (ethanol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol)
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:	In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.
Structural measures to prevent exposure:	In accordance with Section 7.

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	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation. Use non-sparking ventilation system. Provide appropriate personal protective equipment, safety shower and eye-wash station.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield (EN ISO 16321-1:2022, EN 166).
8.2.2.2.	Skin protection	
	Hand protection:	Use appropriate, chemical-resistant protective gloves (EN 374).
	Other skin protection:	Use appropriate protective clothing.
8.2.2.3.	Respiratory protection:	In case of normal usage and ventilation, it is not necessary. If concentration of ethyl alcohol exceeds occupational exposure limits in the air, use a self-contained breathing apparatus. For short contact and if the oxygen content of the air is greater than 18 %, use a protective gas mask with filter A (EN 14837/A1).
8.2.2.4.	Thermal hazards:	No thermal hazards known.
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/odour threshold:	ethanol like/no information available	No information available
Melting point / freezing point:	No information available	No information available

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	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	lower: 3.3 Vol % upper: 19 Vol %	No information available
	Flash point:	13 °C	No information available
	Auto-ignition temperature:	363 °C	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	in water completely miscible	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	0.79 – 0.7921 (20°C)	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	Explosive properties: the vapours from ethyl alcohol form an explosive mixture with air		

SECTION 10. Stability and reactivity		
10.1	Reactivity:	See Section 10.5.
10.2	Chemical stability:	Stable within normal temperature and general work conditions.
10.3	Possibility of hazardous reactions:	See Section 10.5.
10.4	Conditions to avoid:	Keep away from heat, sparks, open flames, strong heating and ignition sources. No smoking.
10.5	Incompatible materials:	Strong oxidizing agents (inorganic strong acid, nitric acid, perchlorates, peroxy compounds, perchloric acid, permanganates etc.), alkali metals, alkali earth metals.
10.6	Hazardous decomposition products:	Carbon monoxide and carbon dioxide.

SECTION 11. Toxicological information					
11.1	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results

Trading name:	HISTANOL 100				
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Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	rabbit (ethanol)	LD ₅₀	-	>20.000 mg/l
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	>8.000 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

	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:	Absorption of great quantities may cause dizziness, drunkenness, euphoria, unconsciousness and alcohol poisoning. In case of swallowing great quantities, nausea and vomiting may occur. Repeated or prolonged exposure may lead to liver cirrhosis.
Dermal exposure:	After prolonged or repeated exposure symptoms may include: defatting, dryness and cracking of skin.
Inhalation exposure:	Inhalation of great quantities may cause dizziness, euphoria and mild irritation of the mucous membranes.
Eye exposure:	May cause irritation and redness.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
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Trading name:	HISTANOL 100				
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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	-

Trading name:	HISTANOL 100				
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	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.	
11.2	Information on other hazards:	
11.2.1.	Endocrine disrupting properties:	
	Based on available data, does not contain endocrine disruptors.	
11.2.2.	Other information:	
	-	

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	golden orf	No information available	8.140 mg/l / 48 h (ethanol)	-
Crustacea:	EC ₅₀	48 hours	daphnia magna	No information available	7.800 mg/l (ethanol)	-
Algae/aquatic plants	IC ₅₀	4 days	algae	No information available	5.000 mg/l / 7d (ethanol)	-
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
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
Log Pow: ~ 0.32	-	-	-	-	-	The product does not bioaccumulate

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
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BCF: 0.66	No information available	No information available	No information available	-

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

12.4	Mobility in soil					
	Known or predicted distribution in environmental compartments:					
	No information available					
	Surface tension:					
	Value	°C	Concentration	Method	Note	
	No information available	No information available	No information available	No information available	-	

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

12.5	Results of PBT and vPvB assessment				
	Based on available data, the product does not contain any PBT or vPvB substances.				

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12.6.	Endocrine disrupting properties
	Based on available data, does not contain endocrine disruptors.
12.7.	Other adverse effects
	Do not let the product or its residues reach sewer system, waterways and soil.
SECTION 13. Disposal considerations	
13.1	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances
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. Unused product residues may be burnt.
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

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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
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

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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:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	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:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
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: 225	Highly flammable liquid and vapor.
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>

ANNEX: Exposure scenario resulting to chemical safety assessment
-

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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. Unsuitable for human consumption.
	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:	-

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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, hot sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P403+P235 Store in a well-ventilated place. Keep cool.
Supplemental hazard information (EU):	-
2.3	Other hazards
	The product has no other known specific hazards for human or environment. Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances. Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.

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- 0147	~ 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:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.
Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.

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	Following eye contact:	In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 10 minutes). If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Place the victim in a comfortable position. Rinse the mouth with clean water. If the victim is conscious induce vomiting. Do not give the victim anything orally, and do not induce vomiting if the victim is unconscious or suffers from convulsions.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.
	Following eye contact:	May irritate the eyes.
	Following ingestion:	Ingestion of larger quantities may affect the central nervous system.
4.3	Indication of any immediate medical attention and special treatment needed	
	If larger quantities have entered the body, obtain medical treatment (gastric lavage, activated carbon).	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Extinguishing powder, alcohol-resistant foam, water, carbon-dioxide.
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Highly flammable liquid and vapour. In case of fire, smoke, and other combustion products (carbon monoxide, carbon dioxide) may be formed, the inhalation of such combustion products can have serious adverse effects on health. Vapours may form an explosive mix with air. Vapours may be ignited by open flames, sparks, electrical equipment, or static charge. Vapours may travel to great distances, ignite in contact with ignition sources and flash back to the primer source (container). Vapours of ethyl alcohol mix greatly with air and may form an explosive mixture. Air containing 3.3 – 19 % ethyl alcohol vapours may explode in contact with ignition sources. Diluting the mixture with large amounts of water results in the loss of its flammability (around 10 % concentration of ethyl alcohol).
5.3	Advice for firefighters	
	Wear full protective clothing and self-contained breathing apparatus. Cool the fire affected containers with water spray. Use water spray to dissipate alcohol vapours.	
5.4	Additional information	
	-	

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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.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.	
6.2	Environmental precautions:	
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.	
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:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).
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

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	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use non-sparkling tools and equipment.
	Measures to prevent aerosol and dust generation:	Ensure adequate 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:	Store in a well-ventilated place, protected from sunlight, away from sources of heat and ignition, in its original, unopened and hermetically sealed packaging, away from oxidizing agents, food, feed and articles of consumption.
	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:	-			

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EC No:	-	CAS No:	-	
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DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	1900 mg/m ³ (ethanol)	-	-	380 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	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m ³ (ethanol)	-	-	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	2.9 mg/kg (ethanol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol)
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:	In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.
	Structural measures to prevent exposure:	In accordance with Section 7.

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	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation. Use non-sparking ventilation system. Provide appropriate personal protective equipment, safety shower and eye-wash station.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield (EN ISO 16321-1:2022, EN 166).
8.2.2.2.	Skin protection	
	Hand protection:	Use appropriate, chemical-resistant protective gloves (EN 374).
	Other skin protection:	Use appropriate protective clothing.
8.2.2.3.	Respiratory protection:	In case of normal usage and ventilation, it is not necessary. If concentration of ethyl alcohol exceeds occupational exposure limits in the air, use a self-contained breathing apparatus. For short contact and if the oxygen content of the air is greater than 18 %, use a protective gas mask with filter A (EN 14837/A1).
8.2.2.4.	Thermal hazards:	No thermal hazards known.
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/odour threshold:	ethanol like/no information available	No information available
Melting point / freezing point:	No information available	No information available

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	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	lower: 3.3 Vol % upper: 19 Vol %	No information available
	Flash point:	13 °C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	in water completely miscible	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	~ 0.805 (20°C)	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	Explosive properties: the vapours from ethyl alcohol form an explosive mixture with air		

SECTION 10. Stability and reactivity		
10.1	Reactivity:	See Section 10.5.
10.2	Chemical stability:	Stable within normal temperature and general work conditions.
10.3	Possibility of hazardous reactions:	See Section 10.5.
10.4	Conditions to avoid:	Keep away from heat, sparks, open flames, strong heating and ignition sources. No smoking.
10.5	Incompatible materials:	Strong oxidizing agents (inorganic strong acid, nitric acid, perchlorates, peroxy compounds, perchloric acid, permanganates etc.), alkali metals, alkali earth metals.
10.6	Hazardous decomposition products:	Carbon monoxide and carbon dioxide.

SECTION 11. Toxicological information					
11.1	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results

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Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	rabbit (ethanol)	LD ₅₀	-	>20.000 mg/l
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	>8.000 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

	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:	Absorption of great quantities may cause dizziness, drunkenness, euphoria, unconsciousness and alcohol poisoning. In case of swallowing great quantities, nausea and vomiting may occur. Repeated or prolonged exposure may lead to liver cirrhosis.
Dermal exposure:	After prolonged or repeated exposure symptoms may include: defatting, dryness and cracking of skin.
Inhalation exposure:	Inhalation of great quantities may cause dizziness, euphoria and mild irritation of the mucous membranes.
Eye exposure:	May cause irritation and redness.

Repeated dose toxicity (subacute, subchronic, chronic)

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

Specific 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	-

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	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.
11.2	Information on other hazards:	
11.2.1.	Endocrine disrupting properties:	
	Based on available data, does not contain endocrine disruptors.	
11.2.2.	Other information:	
	-	

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	golden orf	No information available	8.140 mg/l / 48 h (ethanol)	-
Crustacea:	EC ₅₀	48 hours	daphnia magna	No information available	7.800 mg/l (ethanol)	-
Algae/aquatic plants	IC ₅₀	4 days	algae	No information available	5.000 mg/l / 7d (ethanol)	-
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
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
Log Pow: ~ 0.32	-	-	-	-	-	The product does not bioaccumulate

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
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BCF: 0.66	No information available	No information available	No information available	-

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

12.4	Mobility in soil					
	Known or predicted distribution in environmental compartments:					
	No information available					
	Surface tension:					
	Value	°C	Concentration	Method	Note	
	No information available	No information available	No information available	No information available	-	

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

12.5	Results of PBT and vPvB assessment				
	Based on available data, the product does not contain any PBT or vPvB substances.				

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12.6.	Endocrine disrupting properties
	Based on available data, does not contain endocrine disruptors.
12.7.	Other adverse effects
	Do not let the product or its residues reach sewer system, waterways and soil.
SECTION 13. Disposal considerations	
13.1	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances
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. Unused product residues may be burnt.
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

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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
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	
-	

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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:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	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:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
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: 225	Highly flammable liquid and vapor.
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>

ANNEX: Exposure scenario resulting to chemical safety assessment

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Trading name:	HEMATOXYLIN G2				
Product code:	HEMG2-OT-X**	Revision date:	03 April 2023	Version:	8


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.	Label elements	
	Product identification:	HEMATOXYLIN G2
	Identification number:	-
	Authorization no.:	-

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Hazard pictograms:		
	GHS07	
Signal word:	Warning	
Hazard statements:	H302 Harmful if swallowed.	
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/face protection. P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.	
Supplemental hazard information (EU):	-	
2.3.	Other hazards	
	Endocrine Disrupting Properties: No known endocrine disrupting properties Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.	

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 - 45 %	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.

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	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. If the symptoms persist, immediately call a physician.
	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).

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	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.
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	
	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 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	

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	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:	-

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION				
8.1.	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m³	
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				

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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
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 standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.11 mm Break through time: >480 min

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	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:	dark red	No information available
Odour/odour threshold:	very mild vinegar odour/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
Flash point:	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
pH:	No information available	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density	No information available	No information available

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	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
	-		

SECTION 10 STABILITY AND REACTIVITY

10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
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 hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	anhydrous (ECHA)	rabbit	LD ₅₀	-	7.712 mg/kg (ethylene glycol)
Dermal exposure:	anhydrous (ECHA)	rat	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

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Skin irritation:	-	rabbit	-	-	Slight irritation (ethylene glycol)
Eye irritation:	24 h	rabbit	-	-	Slight irritation (ethylene glycol)

Sensitization					
---------------	--	--	--	--	--

Dermal exposure:	No information available				
Inhalation exposure:	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:	Causes serious eye damage				

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	-

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.
Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	Current <i>in vivo</i> tests did not indicate mutagenic effects.
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.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
	-

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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	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:	03 April 2023	Version:	8

12.3.	Bioaccumulative potential
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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 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
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	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					
Based on available data, the product does not contain any PBT or vPvB substances.					
12.6. Endocrine disrupting properties					
No known endocrine disrupting properties that affect the environment.					
12.7. Other adverse effects					
No adverse effects are expected.					
SECTION 13 DISPOSAL CONSIDERATIONS					
13.1. Waste treatment methods					
13.1.1. 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.					

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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. 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):	-
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:	-

Trading name:	HEMATOXYLIN G2				
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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: The product is not subject to classification.	

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

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15.2.	Chemical safety assessment
	None

SECTION 16 Other information

16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
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: 302	Harmful if swallowed.
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT
-

Trading name:	BLUING REAGENT			
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7

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:	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 identification

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

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

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:	No information available
	Following skin contact:	No information available
	Following eye contact:	No information available
	Following ingestion:	No information available
4.3.	Indication of any immediate medical attention and special treatment needed	

Trading name:	BLUING REAGENT			
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7

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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).	
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.

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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	
	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 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)	

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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	
-	-	-	-	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

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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:	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

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9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Color:	light blue	No information available
	Odour/odour threshold:	no information available/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	>8.0	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
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
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Trading name:	BLUING REAGENT				
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version:	7

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008					
Acute toxicity:					
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		-
Aspiration hazard:		No information available			
Irritation and corrosion:					
	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	-	-	-	-
Eye irritation:	-	-	-	-	-
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 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.				

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

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

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-

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Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)			
Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.		
Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.		
Genotoxicity:	No information available		
Mutagenicity <i>in-vivo</i> :	Current <i>in vivo</i> tests did not indicate mutagenic effects.		
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:	-
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11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
	-

SECTION 12. Ecological information						
12.1.	Toxicity					
Acute 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 (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

Trading name:	BLUING REAGENT					
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version:	7	

Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

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

Biodegradation

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

12.3. Bioaccumulative potential

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

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

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
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Trading name:	BLUING REAGENT				
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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	-
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 K _{ow}	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					

Trading name:	BLUING REAGENT			
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7

12.6.	Endocrine disrupting properties
	No known endocrine disrupting properties that affect the environment.
12.7.	Other adverse effects
	No adverse effects are expected.
SECTION 13. Disposal considerations	
13.1.	Waste treatment methods
13.1.1.	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	
	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-

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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:	-
Further information:	
The product is not subject to classification.	

SECTION 15. Regulatory information

Trading name:	BLUING REAGENT			
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7

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

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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:		-
16.7.	Further information:		<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment
-

Trading name:	EOSIN Y 2% ALCOHOLIC			
Product code:	EOYA-20-OT-X**	Date of compilation:	14 November 2022	Version: 2


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:	-

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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
	Endocrine Disrupting Properties: No known endocrine disrupting properties Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index 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- 0147	70-90 %	ethanol	Flam. Liq. 2; H225
64-19-7/ 200-580-7/ 607-002-00-6	-	0.2 – 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.

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Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
Following ingestion:	Rinse the 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
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Trading name:	EOSIN Y 2% ALCOHOLIC			
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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.
	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:	

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	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.
	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	1900 mg/m ³ (ethanol)	-	-	380 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	

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Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m ³ (ethanol)	-	-	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	2.9 mg/kg (ethanol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol)
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	

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	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.
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/odour threshold:	ethanol like/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	21 °C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available

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pH:	5.4 -5.7	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density:	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available

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 hazard classes as defined in Regulation (EC) No 1272/2008				
	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:	-	rabbit (ethanol)	LD ₅₀	-	>20.000 mg/kg
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	>8.000 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	-

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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:	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.
--	---

11.2	Information on other hazards:
11.2.1.	Endocrine disrupting properties:

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	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
	-

SECTION 12. Ecological information							
12.1	Toxicity						
Acute (short-term) toxicity		Dose	Exposure time	Species	Method	Evaluation	Note
Fish		LC ₅₀	96 hours	Golden orf	No information available	8.140 mg/l /48 h (ethanol)	-
Crustacea:		EC ₅₀	48 hours	Daphnia magna	No information available	7.800 mg/l (ethanol)	-
Algae/aquatic plants		IC ₅₀	4 days	No information available	No information available	5.000 mg/l / 7d (ethanol)	-
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		-

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Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

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

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

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

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

Trading name:	EOSIN Y 2% ALCOHOLIC				
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12.4	Mobility in soil					
	Known or predicted distribution in environmental compartments:					
	No information available					
	Surface tension:					
	Value	°C	Concentration	Method	Note	
	No information available	No information available	No information available	No information available	-	
	Adsorption / desorption					
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-water	No information available		No information available	No information available	No information available	-
Water-air	No information available		No information available	No information available	No information available	-
Soil-air	No information available		No information available	No information available	No information available	-
12.5.	Results of PBT and vPvB assessment					
	Based on available data, the product does not contain any PBT or vPvB substances.					
12.6.	Endocrine disrupting properties					
	Based on available data, does not contain endocrine disruptors.					
12.7	Other adverse effects					
	No adverse effects are expected.					
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.					

Trading name:	EOSIN Y 2% ALCOHOLIC			
Product code:	EOYA-20-OT-X**	Date of compilation:	14 November 2022	Version: 2

13.1.2.	Waste codes/waste designations according to Law:
	15 01 10*: 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.
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

Trading name:	EOSIN Y 2% ALCOHOLIC			
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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
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:	-

Trading name:	EOSIN Y 2% ALCOHOLIC			
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Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
National legislation:	<p>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</p>
15.2	Chemical safety assessment
	None

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

Trading name:	EOSIN Y 2% ALCOHOLIC			
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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
-

Trade name:	BIOMOUNT NEW LOW			
Product code:	BMNL-X**	Date of compilation:	14 November 2022	Version: 4


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:	-

Trade name:	BIOMOUNT NEW LOW			
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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:	P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P331 Do NOT induce vomiting. P405 Store locked up. P501 Dispose of contents and container in accordance with local regulations.
Supplemental hazard information (EU):	-
2.3.	Other hazards
Environmental Hazards: No significant hazards. Material does not meet the criteria for PBT or vPvB in accordance with REACH Annex XIII. Endocrine Disrupting Properties: No known endocrine disrupting properties.	

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:	Immediately remove from further exposure. Get immediate medical assistance. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. Give supplemental oxygen, if available. If breathing has stopped, assist ventilation with a mechanical device.

Trade name:	BIOMOUNT NEW LOW			
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	Following skin contact:	Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse.
	Following eye contact:	Flush thoroughly with water. If irritation occurs, get medical assistance.
	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:	No important symptoms or effects.
	Following skin contact:	No important symptoms or effects.
	Following eye contact:	No important symptoms or effects.
	Following ingestion:	No important symptoms or effects.
4.3.	Indication of any immediate medical attention and special treatment needed	
	If ingested, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Use water fog, foam, dry chemical or carbon dioxide (CO ₂) to extinguish flames.
	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. Prevent run-off from fire control or dilution from entering streams, sewers or drinking water supply. Fire-fighters should use standard protective equipment and in enclosed spaces, self-contained breathing apparatus (SCBA). 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:	See Section 8 for advice on the minimum requirements for personal protective equipment. Additional protective measures may be necessary, depending on the specific circumstances and/or the expert judgment of the emergency responders.

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	Accident prevention methods:	Avoid contact with spilled material. Warn or evacuate occupants in surrounding and downwind areas if required, due to toxicity or flammability of the material. See Section 5 for fire fighting information.
	Emergency procedures:	See the Hazard Identification Section for Significant Hazards. See Section 4 for First Aid Advice.
6.1.2.	For emergency responders:	
	Respiratory protection: half-face or full-face respirator with filter(s) for organic vapor and, when applicable, H ₂ S, or self contained breathing apparatus (SCBA) can be used depending on the size of spill and potential level of exposure. If the exposure cannot be completely characterized or an oxygen deficient atmosphere is possible or anticipated, SCBA is recommended. Work gloves that are resistant to aromatic hydrocarbons are recommended. Note: gloves made of polyvinyl acetate (PVA) are not water-resistant and are not suitable for emergency use. Chemical goggles are recommended if splashes or contact with eyes is possible. Small spills: normal antistatic work clothes are usually adequate. Large spills: full body suit of chemical resistant, antistatic material is recommended.	
6.2.	Environmental precautions:	
	Large Spills: Dyke far ahead of liquid spill for later recovery and disposal. Prevent entry into waterways, sewers, basements or confined areas.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Land Spill: Stop leak if you can do so without risk. Water Spill: Stop leak if you can do so without risk. Confine the spill immediately with booms. Warn other shipping. Remove from the surface by skimming or with suitable absorbents. Seek the advice of a specialist before using dispersants.
6.3.2.	Cleaning up:	Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers. Recover by pumping or with suitable absorbent.
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:	Avoid contact with skin. Prevent small spills and leakage to avoid slip hazard. Material can accumulate static charges which may cause an electrical spark (ignition source).

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	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	When the material is handled in bulk, an electrical spark could ignite any flammable vapors from liquids or residues that may be present (e.g., during switch-loading operations). Use proper bonding and/or earthing procedures.
	Other measures:	This material is a static accumulator. A liquid is typically considered a nonconductive, static accumulator if its conductivity is below 100 pS/m (100x10E-12 Siemens per meter) and is considered a semiconductive, static accumulator if its conductivity is below 10,000 pS/m. Whether a liquid is nonconductive or semiconductive, the precautions are the same. A number of factors, for example liquid temperature, presence of contaminants, anti-static additives and filtration can greatly influence the conductivity of a liquid.
7.1.2.	Advice on general occupational hygiene:	
	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Discard contaminated clothing and footwear that cannot be cleaned. Practice good housekeeping.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in a cool and well-ventilated area.
	Packaging materials:	Teflon, polypropylene, stainless steel, carbon steel.
	Requirements for storage rooms and vessels:	The type of container used to store the material may affect static accumulation and dissipation. Keep container closed. Handle containers with care. Open slowly in order to control possible pressure release.
	Advices for storage equipment:	Storage containers should be earthed and bonded. Fixed storage containers, transfer containers and associated equipment should be earthed and bonded to prevent accumulation of static charge.
	Further information on storage conditions:	Suitable materials and coating are carbon steel, stainless steel, teflon, polyethylene, polypropylene. Unsuitable materials and coatings: butyl rubber, natural rubber, ethylene-propylene-diene monomer (EPDM), polystyrene
7.3.	Specific end use(s)	
	Recommendations:	Section 1 informs about identified end-uses.
	Industrial sector specific solutions:	-

Trade name:	BIOMOUNT NEW LOW			
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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	
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:
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

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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-proof 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:	If contact is likely, safety glasses with side shields are recommended.
8.2.2.2.	Skin protection	
	Hand protection:	If prolonged or repeated contact is likely, chemical-resistant gloves are recommended. If contact with forearms is likely, wear gauntlet-style gloves. Nitrile, minimum 0.38 mm thickness or comparable protective barrier material with a high performance level for continuous contact use conditions, permeation breakthrough minimum 480 minutes in accordance with CEN standards EN 420 and EN 374.
	Other skin protection:	If prolonged or repeated contact is likely, chemical, and oil resistant clothing is recommended.
8.2.2.3.	Respiratory protection:	<p>If engineering controls do not maintain airborne contaminant concentrations at a level which is adequate to protect worker health, an approved respirator may be appropriate. Respirator selection, use, and maintenance must be in accordance with regulatory requirements, if applicable. Types of respirators to be considered for this material include:</p> <p>Half-face filter respirator Type A filter material, European Committee for Standardization (CEN) standards EN 136, 140 and 405 provide respirator masks and EN 149 and 143 provide filter recommendations.</p> <p>For high airborne concentrations, use an approved supplied-air respirator, operated in positive pressure mode. Supplied air respirators with an escape bottle may be appropriate when oxygen levels are inadequate, gas/vapour warning properties are poor, or if air purifying filter capacity/rating may be exceeded.</p>
8.2.2.4.	Thermal hazards:	No information available.
8.2.3.	Environmental exposure controls	

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Substance/mixture related measures to prevent exposure:	Comply with applicable environmental regulations limiting discharge to air, water and soil. Protect the environment by applying appropriate control measures to prevent or limit emissions.
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/odour threshold:	no odour/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	188°C - 210 °C	ASTM D86
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
Flash point:	62 °C	ASTM D-93
Auto-ignition temperature:	222 °C	ASTM E659
Decomposition temperature:	No information available	No information available
pH:	Not technically feasible	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	Negligible	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available

9.2. Other information

-		

Trade name:	BIOMOUNT NEW LOW			
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SECTION 10.: Stability and reactivity

10.1.	Reactivity:	No information available
10.2.	Chemical stability:	The product is stable under normal conditions.
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:	Material does not decompose at ambient temperatures.

SECTION 11. Toxicological information

11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	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	-	Minimally toxic.
Dermal:	No information available	rabbit	LD ₅₀ > 5000 mg/kg	-	Minimally toxic.
Inhalation:	No information available	rat	LC ₅₀ > 5000 mg/ m ³	8 h	Minimally toxic.
	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:		May be fatal if swallowed and enters airways relates to potential for aspiration, a non-quantifiable hazard determined by physico-chemical properties (i.e. viscosity) that can occur during ingestion and also if it is vomited following ingestion. A DNEL cannot be derived. Risks from the physicochemical hazards of substances can be controlled by implementing risk management measures. For substances classified as H304, the following measures need to be implemented to control the aspiration hazard. Do not ingest. If swallowed then seek immediate medical attention. Do NOT induce vomiting.		
	Irritation and corrosion				
	Exposure time		Species	Evaluation	Method
					Note

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Skin corrosion/irritation	No information available	-	Not irritating.	-	-
Serious eye damage/irritation	No information available	-	Not irritating.	-	-

Sensitization					
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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					
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Oral exposure:	May be fatal if swallowed and enters airways.
Dermal exposure:	May dry the skin leading to discomfort and dermatitis.
Inhalation exposure:	Negligible hazard at ambient/normal handling temperatures.
Eye exposure:	May cause mild, short-lasting discomfort to eyes.

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):						
---	--	--	--	--	--	--

	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:	Not expected to cause cancer. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline 453.					
Mutagenicity <i>in-vitro</i> :	No information available					
Genotoxicity:	No information available					
Mutagenicity <i>in-vivo</i> :	No information available					
Germ cell mutagenicity:	Not expected to be a germ cell mutagen. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline 471 473 474 476 478 479.					

Trade name:	BIOMOUNT NEW LOW				
Product code:	BMNL-X**	Date of compilation:	14 November 2022	Version:	4

	Reproductive toxicity:	Not expected to be a reproductive toxicant. Based on test data for structurally similar materials. Test(s) equivalent or similar to OECD Guideline 413 414 415.
	Summary of evaluation of the CMR properties:	No information available
11.2.	Information on other hazards:	
11.2.1.	Endocrine disrupting properties:	
	No known endocrine disrupting properties that affect human health.	
11.2.2.	Other information:	
	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	Oncorhynchus mykiss	No information available	-	1000 mg/l
Crustacea:	EC ₅₀	48 hours	Daphnia magna	No information available	-	1000 mg/l
Algae/aquatic plants:	IC ₅₀	72 hours	Pseudokirchneriella subcapitata	No information available	-	1000 mg/l
Other organisms:	-	-	-	-	-	-
Chronic (long-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	-	-

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Algae/aquatic plants:	IC ₅₀	72 hours	No information available	No information available	-	-
Other organisms:	-	21 day(s)	Daphnia magna	-	-	NOELR 1 mg/l

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
Percent Degraded 31.3: similar material	28 day (s)	Ready Biodegradability (water)	No information available	Expected to be inherently biodegradable

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

Value	Concentration	pH	°C	Method	Evaluation	Note
> 4	No information available	-	-	Estimated	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						
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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						
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Known or predicted distribution in environmental compartments:						

Surface tension:						
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Value	°C	Concentration	Method	Note
No information available	No information available	No information available	No information available	Highly volatile, will partition rapidly to air. Not expected to partition to sediment and wastewater solids.

Adsorption / desorption						
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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	-

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Soil-Air	No information available	No information available	No information available	No information available	-
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12.5.	Results of PBT and vPvB assessment
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	Material does not meet the Reach Annex XIII criteria for PBT or vPvB.
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12.6.	Endocrine disrupting properties
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	No known endocrine disrupting properties that affect the environment.
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12.7.	Other adverse effects
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	No adverse effects are expected.
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SECTION 13. Disposal considerations
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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. 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.
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13.1.2.	Waste codes/waste designations according to Law:
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	The European Waste Catalogue (EWC) code is specific to the waste generating process and waste constituents. Determine the EWC according to the criteria provided in the European Waste Catalogue and the hazardous waste list established by Commission Decision 2000/532/EC, as amended.
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13.1.3.	Waste treatment – relevant information:
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	Disposal recommendations based on material as supplied. Disposal must be in accordance with current applicable laws and regulations, and material characteristics at time of disposal.
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13.1.4.	Sewage disposal – relevant information:
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	Product is suitable for burning in an enclosed controlled burner for fuel value or disposal by supervised incineration at very high temperatures to prevent formation of undesirable combustion products.
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13.1.5.	Other disposal recommendations:
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	Empty Container Warning (where applicable): 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)	
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:	-	

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

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National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
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15.2.	Chemical safety assessment
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SECTION 16. Other information

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

ANNEX: Exposure scenario resulting to Chemical safety assessment
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