RAPID PAP STAINING KIT

The kit contains:

Histanol 95
Deionized water
Hematoxylin HP, Pap 1A
Bluing reagent
OG-6 reagent, Pap 2A
EA 50 reagent, Pap 3B
Histanol 100
BioClear New
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 *in vitro* 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.
	Supplemetal 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 (CO2) 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

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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, H2S, 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-proplyene-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/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

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Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

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

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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.

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.	-	-

Sensitization

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

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	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	-

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

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

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

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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 *in-vitro*:	No information available
	Genotoxicity:	No information available
	Mutagenicity *in-vivo*:	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 informations:
	Vapour concentration above recommended exposure levels are irritating to the eyes and the respiratory tract, may cause headaches and dizziness, are anasthetic 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 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
	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

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:
	-

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

SECTION 16. Other information		
16.1.	Indication of changes:	Composition: Component Table for REACH information was modified. Section 09 median particle size information was added. Section 09: Freezing Point °C(°F) information was deleted. Section 09: Melting Point °C (F) information was deleted. Section 11 EU Annex II Endocrine Disruptor Data information was added. Section 12 EU Annex II Endocrine Disruptor Data information was added. Section 2 EU Annex II Endocrine Disruptor Data information was added. Section 9 melting and freezing points information was added.

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16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
Classification		Classification procedure
-		-
16.5.	Relevant H statements (number and full text)	
	H: 304 (EUH066)	May be fatal if swallowed and enters airways. Repeated exposure may cause skin dryness or cracking.
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment

-

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 *in vitro* diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Warning statements*:
	Aspir. Tox. 1	H304
2.1.2.	Additional information	
	EUH066	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	BIOMOUNT NEW LOW
	Identification number:	-
	Authorisation number:	-

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	Hazard pictograms:	 GHS08
	Signal word:	Danger
	Hazard statement:	H304 May be fatal if swallowed and enters airways. EUH066 Repeated exposure may cause skin dryness or cracking.
	Precautionary statements:	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.
	Supplemetal 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.

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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 (CO2) 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, H2S, 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-proplyene-diene monomer (EPDM), polystyrene
7.3.	Specific end use(s)	
	Recommendations:	Section 1 informs about identified end-uses.
	Industrial sector specific solutions:	-

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SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m^3	
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-proff ventilation equipment.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	See Section 7.2
8.2.2.	Personal protection equipment:	
8.2.2.1.	Eye and face protection:	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:	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: 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. 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.
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		
	-		

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

Symptoms related to the physical, chemical and toxicological characteristics	
Oral exposure:	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 *in-vitro*:	No information available
Genotoxicity:	No information available
Mutagenicity *in-vivo*:	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.

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	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 informations:	
	Vapour concentration above recommended exposure levels are irritating to the eyes and the respiratory tract, may cause headaches and dizziness, are anasthetic 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

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.

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	-

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Soil-Air	No information available	No information available	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
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.
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:

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

SECTION 16. Other information		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
Classification		Classification procedure
-		-
16.5.	Relevant H statements (number and full text)	
	H: 304 (EUH066)	May be fatal if swallowed and enters airways. Repeated exposure may cause skin dryness or cracking.
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment
-

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 *in vitro* 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:	-
	Supplemetal 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	

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

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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

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

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	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection

8.1. Control 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) acording 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:	ight 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

Trading name:	**BLUING REAGENT**				
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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)

	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 *in-vitro:*	Current *in vitro* tests did not indicate mutagenic effects.
	Genotoxicity:	No information available
	Mutagenicity *in-vivo*:	Current *in vivo* tests did not indicate mutagenic effects.
	Germ cell mutagenicity:	No information available
	Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.

	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 informations:
	-

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 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

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

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	-

Adsorption / desorption

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

12.5. Results of PBT and vPvB assessment

No information available

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

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

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:	** "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:	**EA 50 REAGENT, PAP 3B**				
Product code:	EA50-OT-X**	Date of compilation:	10 July 2024	Version:	5

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1.	Product identifier	
	Trade name:	EA 50 REAGENT, PAP 3B
	Chemical name:	-
	Catalogue number:	EA50-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Cytoplasmic staining reagent acc. to Papanicolaou.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an *in vitro* 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 Acute Tox. 4	H225 H302
2.1.2.	Additional information	
	-	

*For full text of Hazard- and EU Hazard-statements: see Section 16.

2.2.	Label elements	
	Product identification:	EA 50 REAGENT, PAP 3B
	Identification number:	-

Trade name:	**EA 50 REAGENT, PAP 3B**				
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	Authorisation number:	-
	Hazard pictograms:	 GHS02  GHS07
	Signal word:	Danger
	Hazard statement:	H225 Highly flammable liquid and vapour. H302 Harmful if swallowed.
	Precautionary statement:	P210 Keep away from heat, hot surfaces, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P501 Dispose of contents/container to an approved waste disposal plant.
	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
107-21-1/ 203-473-3/ 603-027-00-1	-	15-25%	ethylene glycol	Acute Tox. 4; H302

SECTION 4. First aid measures

4.1.	Description of first aid measures

Trade name:	**EA 50 REAGENT, PAP 3B**				
Product code:	EA50-OT-X**	Date of compilation:	10 July 2024	Version:	5

	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove all contaminated clothes/footwear. Thoroughly wash with water for at least 15 minutes.
	Following eye contact:	Rinse the eyes using mild jet of clean water for at least 20 minutes with the eyelids held wide open.
	Following swallowing:	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 swallowing:	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	
	No information available	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, alcohol-resistant foam, 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 byproducts of fire:	Incomplete combustion of the product.
5.3.	Advice for firefighters	
	Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing).	
5.4.	Additional information	

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	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.

SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112). 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.

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	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.
	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/-	No information available
Ethylene glycol	107-21-1	20/40	52/104	No information available

Substance:	-		
EC No:	-	CAS No:	-

DNEL

Industrial

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

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Inhalation	1900 mg/m^3 (ethanol)	-	35 mg/ kg (ethylene glycol)	380 mg/m^3 (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol) 106 mg/kg (ethylene glycol)
Critical physical parameters: solubility, flammability, corrosivity:			-	

Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m^3 (ethanol)	-	7 mg/kg (ethylene glycol)	114 mg/m^3 (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol) 53 mg/kg (ethylene glycol)

PNEC	
Environmental protection target	**PNEC**
Fresh water	960 µg/l (ethanol) 10 mg/l (ethylene glycol)
Freshwater sediments	3.6 mg/kg (ethanol) 37 mg/kg (ethylene glycol)
Marine water	790 µg/l (ethanol) 1 mg/l (ethylene glycol)
Marine sediments	2.9 mg/kg (ethanol) 3.7 mg/kg (ethylene glycol)
Food chain	380-720 mg/kg kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol) 199.5 mg/l (ethylene glycol)
Soil (agricultural)	0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene glycol)
Air	no information available

8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment.
	Structural measures to prevent exposure:	No information available

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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:	See Section 7.2
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	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:	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) acording 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:	violet green	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:	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
	pH:	5. 2 – 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:	The product is stable under normal working and storage conditions.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.
10.4.	Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5.	Incompatible materials:	Oxidants, acids, alkali metals.
10.6.	Hazardous decomposition products:	Non-degradable if used in the described manner.

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}	-	7.060 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol)
Dermal:	No information available	rabbit	LD_{50}	-	>20.000 mg/kg (ethanol) >3.500mg/kg (ethylene glycol)
Inhalation:	No information available	rat	LC_{50}	4 h (ethanol)	>8.000 mg/l (ethanol)

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	No information available	No information available	No information available	No information available	-
Serious eye damage/irritation	No information available	No information available	No information available	No information available	-

Sensitization

Skin sensitization:	No information available
Respiratory sensitization:	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)

	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:	No information available
Mutagenicity *in-vitro*:	No information available
Genotoxicity:	No information available
Mutagenicity *in-vivo*:	No information available
Germ cell mutagenicity :	No information available
Reproductive toxicity:	No information available
Summary of evaluation of the CMR properties:	No information available

11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other informations:
	-

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	8.140 mg/l (ethanol) 72.860 mg/l (ethylene glycol)	-
Crustacea:	EC_{50}	48 hours	Daphnia magna	No information available	7.800 mg/l (ethanol) >100 mg/l (ethylene glycol)	-
Algae/aquatic plants:	IC_{50}	72 hours	algae	No information available	5.000 mg/l (ethanol) 6.500-13.000 mg/l (ethylene glycol)	-

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Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	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
-	-	-	-	-

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 (Daphnia)	EC_{50}	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

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

Adsorption / desorption

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

12.5.	Results of PBT and vPvB assessment
	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.
13.1.2.	Waste codes/waste designations according to Low:
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.

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

SECTION 14. Transport information

Transporting/shipment by road (ADR)	
UN number	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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
Environmental hazards:	No information available
Special precautions for user:	-

Transporting/shipment by inland waterways (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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
Environmental hazards:	No information available
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:	1170

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UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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	
	Authorisation and/or restrictions on use	
	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-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	

Trade name:	**EA 50 REAGENT, PAP 3B**				
Product code:	EA50-OT-X**	Date of compilation:	10 July 2024	Version:	5

	None

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

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.
		302	Harmful if swallowed.

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

ANNEX: Exposure scenario resulting to Chemical safety assessment
-

Trading name:	**HEMATOXYLIN HP, PAP 1A**				
Product code:	HEMHP-OT-X**	Revision date:	16 July 2024	Version:	8

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1.	Product identifier	
	Trading name:	HEMATOXYLIN HP, PAP 1A
	Chemical name:	-
	Catalogue number:	HEMHP-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Modified hematoxylin acc. to Harris for nuclear staining acc. to Papanicolaou.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an *in vitro* 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*:
	Eye Dam. 1	H318
2.1.2.	Additional information	
	-	

*For full text of Hazard- and EU Hazard-statements: see Section 16

2.2.	Label elements	
	Product identification:	HEMATOXYLIN HP, PAP 1A
	Identification number:	-
	Authorization no.:	-

Trading name:	**HEMATOXYLIN HP, PAP 1A**				
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	Hazard pictograms:	 GHS05
	Signal word:	Danger
	Hazard statements:	H318 Causes serious eye damage.
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P310 Immediately call POISON CENTER or a doctor/physician if exposed.
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	Endocrine Disrupting Properties: No known endocrine disrupting properties **Results of PBT and vPvB assessment**: According to the results of its assessment, this substance is not a PBT or a vPvB.	

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)
7784-31-8/ 616-524-3/ -	-	9 - 10 %	aluminum sulfate octadecahydrate	Eye Dam. 1; H318
107-21-1/ 203-473-3/ 603-027-00-1	01-2119456816-28-xxxx	≤ 10 %	ethylene glycol	Acute Tox. 4, H302

SECTION 4 FIRST AID MEASURES

4.1.	Description of first aid measures	
	General notes:	-
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.

	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.
	Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.
	Self-protection of the first aider:	Treat symptomatically.
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.	

Trading name:	**HEMATOXYLIN HP, PAP 1A**				
Product code:	HEMHP-OT-X**	Revision date:	16 July 2024	Version:	8

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.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	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 AN STORAGE		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	

	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

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:	Aluminium sulphate octadecahydrate			
EC No:	233-135-0	CAS No:	7784-31-8	

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	13,4 mg/m^3
Dermal	-	-	-	3,8 mg/kg bw/day

Critical physical parameters: solubility, flammability, corrosivity:	-

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

PNEC	
Environmental protection target	**PNEC**
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

8.2.	Exposure controls	
8.2.1.	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
	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) acording 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:	red-purple	No information available
	Odour/odour threshold:	no odor/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	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
	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}	-	>2.000-<5.000 mg/kg (aluminium sulphate octadecahydrate)
Dermal exposure:	anhydrous (ECHA)	rat	LD_{50}	-	>5.000mg/kg (aluminium sulphate octadecahydrate)
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:	-	-	-	-	
Eye irritation:	-	-	-	-	Causes serious eye damage

	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 *in-vitro:*	Current *in vitro* tests did not indicate mutagenic effects.
Genotoxicity:	No information available
Mutagenicity *in-vivo*:	Current *in vivo* tests did not indicate mutagenic effects.
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.

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 informations:

-

Trading name:	**HEMATOXYLIN HP, PAP 1A**				
Product code:	HEMHP-OT-X**	Revision date:	16 July 2024	Version:	8

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	>85.9 mg/l (aluminium sulphate octadecahydrate)	-
Crustacea:	EC_{50}	48 hours	water flea	No information available	>200 mg/l (aluminium sulphate octadecahydrate)	-
Algae/aquatic plants	IC_{50}	8 days	algae	No information available	-	-
Microorganisms	LC_{50}	72 hours	-	-	-	-

Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC_{50}	96 hours	No information available	No information available	No information available	-
Crustacea:	EC_{50}	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC_{50}	72 hours	No information available	No information available	No information available	-
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
	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 (*Daphnia*)	EC_{50}	No information available	No information available	No information available	No information available	-

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

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

Adsorption / desorption

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

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

SECTION 16 Other information		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
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.
	318	Causes serious eye damage.
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: **EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT**
-

Trading name:	**HEMATOXYLIN HP, PAP 1A**				
Product code:	HEMHP-OT-X**	Revision date:	16 July 2024	Version:	8

Trading name:	**HISTANOL 95**				
Product code:	H95-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 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 comsumption.
	Reason why uses advised against:	The product is intended for use only as an *in vitro* 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.
	Supplemetal 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.	Bunding, 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

Trading name:	**HISTANOL 95**				
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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:	-	

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.

	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-sparkling 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 *in vitro*:	Based on available data, the classification criteria are not met.
	Genotoxicity:	Based on available data, the classification criteria are not met.
	Mutagenicity *in vivo*:	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 informations:	
	-	

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 Kow)

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 (*Daphnia*)	EC_{50}	No information available	No information available	No information available	No information available	-

12.4 Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

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

Adsorption / desorption

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

12.5 Results of PBT and vPvB assessment

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:	-

SECTION 15. Regulatory information

Trading name:	**HISTANOL 95**				
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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:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; 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). REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-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:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	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:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to chemical safety assessment
-

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

SECTION 2. Hazards identification		
2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Flam. Liq. 2	H225
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	HISTANOL 100
	Identification number:	-
	Authorization number:	-

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	Hazard pictograms:	 GHS02
	Signal word:	Danger
	Hazard statements:	H225 Highly flammable liquid and vapor.
	Precautionary statements:	P210 Keep away from heat, 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.
	Supplemetal 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	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.

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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.	Bunding, 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

	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:	-	

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.

	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-sparkling 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	

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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 *in vitro*:	Based on available data, the classification criteria are not met.
	Genotoxicity:	Based on available data, the classification criteria are not met.
	Mutagenicity *in vivo*:	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 informations:	
	-	

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	-

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 Kow)

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 (*Daphnia*)	EC_{50}	No information available	No information available	No information available	No information available	-

12.4 Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

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

Adsorption / desorption

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

12.5 Results of PBT and vPvB assessment

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:	-

SECTION 15. Regulatory 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:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; 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). REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-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:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	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:	** "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:	**OG-6 REAGENT, PAP 2A**				
Product code:	OG6-OT-X**	Date of compilation:	14 Nov 2022	Version:	3

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1.	Product identifier	
	Trade name:	OG-6 REAGENT, PAP 2A
	Chemical name:	-
	Catalogue number:	OG6-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Cytoplasmic staining reagent acc. to Papanicolaou.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an *in vitro* 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
2.1.2.	Additional information	
	-	

*For full text of Hazard- and EU Hazard-statements: see Section 16.

2.2.	Label elements	
	Product identification:	OG-6 REAGENT, PAP 2A
	Identification number:	-

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	Authorisation number:	-
	Hazard pictograms:	 GHS02
	Signal word:	Danger
	Warning statement:	H225 Highly flammable liquid and vapor.
	Precautionary statement:	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
107-21-1/ 203-473-3/ 603-027-00-1	-	10-20 %	ethylene glycol	Acute Tox. 4; H302

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 all contaminated clothes/footwear. Thoroughly wash with water for at least 15 minutes.
	Following eye contact:	Rinse the eyes using mild jet of clean water for at least 20 minutes with the eyelids held wide open.
	Following swallowing:	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 swallowing:	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	
	No information available	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, alcohol-resistant foam, 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 byproducts of fire:	Incomplete combustion of the product.
5.3.	Advice for firefighters	
	Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing).	
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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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:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112). Do not use incompatible materials (see Section 10).
6.4.	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	

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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/-	No information available
Ethylene glycol	107-21-1	20/40	52/104	No information available

Substance:	-		
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)	-	35 mg/ kg (ethylene glycol)	380 mg/m^3 (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol) 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	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m^3 (ethanol)	-	7 mg/kg (ethylene glycol)	114 mg/m^3 (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol) 53 mg/kg (ethylene glycol)

PNEC	
Environmental protection target	**PNEC**
Fresh water	0.96 mg/l (ethanol) 10 mg/l (ethylene glycol)
Freshwater sediments	3.6 mg/kg (ethanol) 37 mg/kg (ethylene glycol)
Marine water	0.79 mg/l (ethanol) 1 mg/l (ethylene glycol)
Marine sediments	2.9 mg/kg (ethanol) 3.7 mg/kg (ethylene glycol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol) 199.5 mg/l (ethylene glycol)
Soil (agricultural)	0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene glycol)
Air	no information available

8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment.
	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:	See Section 7.2
8.2.2.	Personal protection equipment	

8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	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:	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) acording 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	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

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	Flash point:	19 °C	no information available
	Auto-ignition temperature:	no information available	no information available
	Decomposition temperature:	no information available	no information available
	pH:	3.0 – 5.5	no information available
	Kinematic viscosity:	no information available	no information available
	Solubility:	no information available	no information available
	Partition coefficient n-octanol/water (log value):	no information available	no information available
	Vapour pressure:	No information available	no information available
	Density and/or relative density:	no information available	no information available
	Relative vapour density:	no information available	no information available
	Particle characteristics:	no information available	no information available
9.2.	Other information		
	-		

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	The product is stable under normal working and storage conditions.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.
10.4.	Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5.	Incompatible materials:	Oxidants, acids, alkali metals.
10.6.	Hazardous decomposition products:	Non-degradable if used in the described manner.

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:		-	rat	LD_{50}	-	7.060 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol)

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Dermal:	-	rabbit	LD_{50}	-	>20.000 mg/kg (ethanol) >3.500mg/kg (ethylene glycol)
Inhalation:	-	rat	LC_{50}	4 h (ethanol)	>8.000 mg/l (ethanol)

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	No information available	No information available	No information available	No information available	-
Serious eye damage/irritation	No information available	No information available	No information available	No information available	-

Sensitization

Skin sensitization:	No information available
Respiratory sensitization:	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.
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.

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No information available
Mutagenicity *in-vitro*:	No information available
Genotoxicity:	No information available
Mutagenicity *in-vivo*:	No information available
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No information available
Summary of evaluation of the CMR properties:	No information available

11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other informations:
	-

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	8.140 mg/l (ethanol) 72.860 mg/l (ethylene glycol)	-
Crustacea:	EC_{50}	48 hours	Daphnia magna	No information available	7.800 mg/l (ethanol) >100 mg/l (ethylene glycol)	-

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Algae/aquatic plants:	IC_{50}	72 hours	algae	No information available	5.000 mg/l (ethanol) 6.500-13.000 mg/l (ethylene glycol)	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	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
-	-	-	-	-

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 (Daphnia)	EC_{50}	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

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

Adsorption / desorption

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

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

12.5.	Results of PBT and vPvB assessment
	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.
13.1.2.	Waste codes/waste designations according to Low:
	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:

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	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
Environmental hazards:	No information available
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
Environmental hazards:	No information available
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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
Environmental hazards:	No information available
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:	1170
UN proper shipping name:	Ethanol solution

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Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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	
	Authorisation and/or restrictions on use	
	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-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	

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SECTION 16. Other information

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

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.
	302	Harmful if swallowed.

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

ANNEX: Exposure scenario resulting to Chemical safety assessment

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