

Trade name:	GIEMSA SOLUTION				
Product code:	GM-OT-X**	Date of compilation:	07 June 2019	Version:	7

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	GIEMSA SOLUTION
	Chemical name:	-
	Catalogue number:	GM-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For staining in hematology, cytology and staining sections of hematopoietic organs in histopathology.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statement*:
	Flam. Liq. 3	H226
	Acute Tox. 3	H301
	Acute Tox. 3	H311
	Acute Tox. 3	H331
	STOT SE 1	H370
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
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Identification number:	-
Authorisation number:	-
Hazard pictograms:	 GHS02  GHS06  GHS08
Signal word:	Danger
Hazard statements:	H226 Flammable liquid and vapor. H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled. H370 Causes damage to organs (eyes).
Precautionary statements:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves, protective clothing, eye protection, face protection. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.
Supplemental hazard information (EU):	-
2.3. Other hazards	-

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

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67-56-1/ 200-659-6/ 603-001-00-X	01-2119433307- 44-xxxx	≥20 %	methanol	Flam. Liq. 2, H225 Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 STOT SE 1, H370
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SECTION 4. First aid measures		
4.1.	Description of first aid measures	
	General notes:	First aider needs to protect himself.
	Following inhalation:	Carry the afflicted person out for fresh air, place them in half lying position and calm them down. If breathing stops, immediately apply artificial respiration, if necessary also oxygen. In case of irregular breathing or respiratory arrest provide artificial respiration.
	Following skin contact:	Remove contaminated clothing. Wash with plenty of water and soap for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse with water and expectorate. Make the afflicted person drink one glass (100 ml) of 40% ethanol (adult dose). Call a doctor immediately (mention methanol ingestion). Only in exceptional cases, if no medical care is available within one hour, induce vomiting (only in fully conscious persons) and make victim drink ethanol again (approx. 0.3 ml of a 40% alcoholic beverage/kg body weight/hour). Do not attempt to neutralise.
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Irritation to the airways and possible damage to the lung probably only through very high vapor concentrations, then even absorptive-toxic effects.
	Following skin contact:	Minor/no irritation, degreasing action, following massive contact watch for danger of skin absorption and possibly delayed onset of systemic effects.
	Following eye contact:	Slight through to moderate irritation due to the liquid and concentrated vapors, conjunctivitis, later chemosis, apparently minor probability of cornea damage, later occurring visual disturbances are caused not primarily through local contact but are systemically related (following absorption).
	Following ingestion:	Stomach and bowel irritation, feeling unwell, nausea, vomiting, strong abdominal pain. Absorption may cause toxic effects.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	water spray, foam, dry powder, CO ₂

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	Unsuitable extinguishing media:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous by products of fire:	Combustible. Vapours are heavier than air and may spread along floors. Forms explosive mixtures with air at ambient temperatures. Development of hazardous combustion gases or vapours possible in the event of fire.
5.3.	Advice for firefighters	
	Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.	
5.4.	Additional information	
	Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.	

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:	Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.s
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not let product enter drains. Risk of explosion.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Cover drains. Collect, bind and pump off spills.
6.3.2.	For cleaning:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.
6.3.3.	Other information:	Do not use tools that may cause sparks.
6.4.	Reference to other sections	

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See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal information.
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SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures for fire prevention:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition and direct sunlight. Do not smoke. Take precautionary measures against static discharge.
	Measures for preventing spray and dust formation:	Secure proper ventilation. Prevent formation of aerosols.
	Environmental precautions:	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, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection		
8.1.	Control parameters	

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Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Methanol	67-56-1	200	260	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*), end-of-shift urinary excretion

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

Substance:	-
EC No:	-
CAS No:	-

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	260 mg/m ³ (methanol)	260 mg/m ³ (methanol)	260 mg/m ³ (methanol)	260 mg/m ³ (methanol)
Dermal	-	40 mg/kg (methanol)		40 mg/kg (methanol)

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	8 mg/kg (methanol)	-	8 mg/kg (methanol)
Inhalation	50 mg/m ³ (methanol)	50 mg/m ³ (methanol)	50 mg/m ³ (methanol)	50 mg/m ³ (methanol)
Dermal	-	8 mg/kg (methanol)		8 mg/kg (methanol)

PNEC

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

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8.2.	Exposure controls	
8.2.1.	Appropriate engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU).
8.2.2.2.	Skin protection:	
	Hand protection:	The protective gloves to be used must comply with the specification of EC Directive 2016/425 and the related standard EN374. Full contact: Glove material: butyl rubber Glove thickness: 0.70 mm Break through time: > 480 min Splash contact: Gloves material: viton (R) Glove thickness: 0.70 mm Break through time: >120 min
	Other skin protection:	Complete antistatic suit protecting against chemicals (EN 13688). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Required when vapours/aerosols are generated. Recommended filter type: gas filter AX, colour code brown (EN 371). The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6

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Structural measures to prevent exposure:	Use modern equipment. Do not let product enter drains. Risk of explosion.
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:	blue-purple	No information available
	Odour:	methanol like	No information available
	Odor threshold:	No information available	No information available
	pH:	6.8 – 7.2 (20 °C)	No information available
	Melting point/freezing point:	No information available	No information available
	Initial boiling point and boiling range:	65 °C (at 1.013 hPa)	No information available
	Flash point:	24 °C	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	lower: 6 % (V) methanol upper: 36.5 % (V) methanol	No information available
	Vapour pressure:	128 hPa	No information available
	Vapour density:	No information available	No information available
	Relative density	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	Soluble in water (20 °C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	Not classified as explosive.	No information available
	Oxidising properties:	No information available	No information available
9.2.	Other information		
	-		

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SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	Vapours may form explosive mixture with air.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	Risk of explosion with: Oxidizing agents, alkali metals, nitric acid, sulphuric acid, hydrogen peroxide, permanganic acid, sodium hypochlorite. The substance can react dangerously with: halogens, oxidizing agents, reducing agents, acids, acetyl bromide, alkylaluminium solutions, beryllium hydride, chloroform, chromium(VI)-oxide, cyanuric chloride, alkaline-earth metals, magnesium splinters, phosphorus trioxide, Raney-nickel/hydrogenation, acid anhydrides, acid halogenides, tetrachloromethane/light metals.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Various plastics, magnesium, zinc alloys, aluminium and galvanised iron.
10.6.	Hazardous decomposition products:	No information available.

SECTION 11. Toxicological information					
11.1.	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	LD ₅₀	-	1,187 -2,769 mg/kg (methanol)
Dermal:	No information available	rabbit	LD ₅₀	-	17.100 mg/kg (methanol)
Inhalation:	No information available	rat	LC ₅₀	4 h	131.25 mg/l (methanol)
	Specific target organ toxicity - single exposure (STOT-SE):				
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		Eyes		mixture causes damage to organs
	Aspiration hazard:		No information available		

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Irritation and corrosion						
Exposure time		Species	Evaluation	Method	Note	
Skin corrosion/irritation	-	-	-	-	drying-out effect resulting in rough and chapped skin	
Serious eye damage/irritation	-	-	-	-	irritations of mucous membranes	
Sensitization						
Skin sensitization:		Does not cause sensitization.				
Respiratory sensitization:		No information available				
Symptoms related to the physical, chemical and toxicological characteristics:						
Oral exposure:		Stomach and bowel irritation, acidosis, drop in blood pressure, feeling unwell, vomiting, strong abdominal pain. Absorption may cause toxic effects. Damage to liver, kidney, cardiac.				
Dermal exposure:		Minimum level of irritation, defatting; prolonged exposure may cause absorption and greater possibility of delayed systemic effects.				
Inhalation exposure:		Airways irritation and possible lung damage due to high levels of vapor concentration, dizziness, drowsiness, headache. Absorption may cause toxic effects.				
Eye exposure:		Mild to moderate irritation due to vapor, conjunctivitis, later chemosis, lesser possibility of cornea damage, blindness, irreversible damage of the optical nerve. Visual impairments may occur later, after the absorption.				
Repeated dose toxicity (subacute, subchronic, chronic)						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-

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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 <i>in-vitro</i> :	No information available	
Genotoxicity:	No information available	
Mutagenicity <i>in-vivo</i> :	No information available	
Germ cell mutagenicity :	No information available	
Reproductive toxicity:	No information available	
Summary of evaluation of the CMR properties; :	No information available	

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11.2.	Practical experiences:	
	Classification observations:	No information available
	Other observations:	No information available
11.3.	General notes:	
	-	

SECTION 12. Ecological information						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	<i>Lepomis macrochirus</i> (Bluegill sunfish)	No information available	No information available	15.400 mg/l (methanol)
Crustacea:	EC ₅₀	48 hours	<i>Daphnia magna</i>	No information available	No information available	>10.0000 mg/l (methanol)
Algae/aquatic plants:	IC ₅₀	8 days	<i>Pseudokirchneriella subcapitata</i> (green algae)	No information available	No information available	22.000 mg/l (methanol)
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
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	-

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Soil	No information available	No information available	No information available	-
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Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
99%	30 days	OECD Test Guideline 301D	No information available	readily biodegradable (methanol)

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

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

Bioconcentration Factor (BCF)

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

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:

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

Adsorption / desorption

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

12.5. Results of PBT and vPvB assessment

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

12.6. Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

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

13.1.2. Waste codes/waste designations according to Law:

No information available

13.1.3. Waste codes/waste designations according to Low:

15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances

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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:
	Disposal must be made according to official regulations.

SECTION 14. Transport information

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

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Packing group:	III
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (methanol solution)
Transport hazard class(es):	3 (6.1)
Packing group:	III
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:
	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)

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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:	PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity – single exposure IMDG International Maritime Dangerous Goods IATA International Air Transport Association GHS Globally Harmonized System of Classification and Labelling of Chemicals
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H: 225 226 301+311+331 370	Highly flammable liquid and vapor. Flammable liquid and vapor. Toxic if swallowed, in contact with skin or if inhaled. Causes damage to organs (eyes).
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:	GIEMSA SOLUTION				
Product code:	GM-OT-X**	Date of compilation:	07 June 2019	Version:	7

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	BUFFER SOLUTION, pH 7.2
	Chemical name:	-
	Catalogue number:	PUF72-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Buffer solution for use in hematology, 6 mM.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	BUFFER SOLUTION, pH 7.2
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	-
	Signal word:	-

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

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

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

SECTION 4. First aid measures		
4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	No information available.
	Following skin contact:	No information available.
	Following eye contact:	No information available.
	Following ingestion:	No information available.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

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

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents.
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	-	

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.

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

	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 at temperatures ranging from 15 to 25 °C.
	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	
-	-	-	-	-
Substance name: -				
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity:

-

Consumer

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

PNEC

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

8.2 Exposure controls

8.2.1. Appropriate engineering controls

Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
Structural measures to prevent exposure:	In accordance with Section 7.
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.

8.2.2. Personal protection equipment

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

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

	Hand protection:	Protective nitrile gloves, 0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Ensure adequate ventilation to the premises where the product is stored and/or handled.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour:	No information available	No information available
	Odor threshold:	No information available	No information available
	pH:	7.2	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	-		

SECTION 10. Stability and reactivity			
10.1	Reactivity:	No information available	
10.2	Chemical stability:	No information available	
10.3	Possibility of hazardous reactions:	No information available	
10.4	Conditions to avoid:	No information available	
10.5	Incompatible materials:	No information available	
10.6	Hazardous decomposition products:	No information available	

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

Trading name:	BUFFER SOLUTION, pH 7.2				
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version:	3

Irritation and corrosion						
Exposure time		Species	Evaluation	Method	Note	
Skin corrosion/irritation:	-	-	-	-	-	
Serious eye damage/irritation	-	-	-	-	-	
Sensitization						
Skin sensitization:		-				
Respiratory sensitization:		-				
Symptoms related to the physical, chemical and toxicological characteristics						
Oral exposure:		No information available				
Dermal exposure:		No information available				
Inhalation exposure:		No information available				
Eye exposure:		No information available				
Repeated dose toxicity (subacute, subchronic, chronic)						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-

Trading name:	BUFFER SOLUTION, pH 7.2				
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version:	3

Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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

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

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	Summary of evaluation of the CMR properties:	No information available
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11.2	Practical experiences:	
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	Classification observations:	No information available
	Other observations:	No information available

11.3	General notes:	
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Trading name:	BUFFER SOLUTION, pH 7.2				
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version:	3

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

Trading name:	BUFFER SOLUTION, pH 7.2				
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3	

No information available	No information available	No information available	No information available	No information available

12.3 Bioaccumulative potential

Octanol-water partition coefficient (log K _{ow})						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	-	-	-	-	-	-

Bioconcentration factor (BCF)

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

Chronic ecotoxicity

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

12.4 Mobility in soil

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

Trading name:	BUFFER SOLUTION, pH 7.2				
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version:	3

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

12.5	Results of PBT and vPvB assessment
	No information available

12.6	Other adverse effects
	No information available

SECTION 13. Disposal considerations

13.1	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
	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.

13.1.6.	Relevant Community provisions:
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Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

-	
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:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

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

SECTION 16. Other information		
16.1	Indication of changes:	-

Trading name:	BUFFER SOLUTION, pH 7.2			
Product code:	PUF72-OT-X**	Date of compilation:	06 June 2019	Version: 3

16.2	Abbreviations and acronyms:	PBT	Stable, bioaccumulative and toxic
		vPvB	Strongly stable and strongly bioaccumulative.
		LD ₅₀	Lethal dose, 50%
		LC ₅₀	Lethal concentration, 50%
		TCOJ	Specific target organ toxicity - single exposure
16.3.	Key literature references and source of data:	-	
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		
	H:	-	-
16.6.	Training advice:	-	
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:	DIFFERENTIATING REAGENT FOR GIEMSA HP KIT			
Product code:	RGHP-OT-X**	Revision date:	12 July 2019	Version: 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	DIFFERENTIATING REAGENT FOR GIEMSA HP KIT
	Chemical name:	-
	Catalogue number:	RGHP-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Giemsa HP kit.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

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

Trading name:	DIFFERENTIATING REAGENT FOR GIEMSA HP KIT			
Product code:	RGHP-OT-X**	Revision date:	12 July 2019	Version: 3

Hazard pictograms:	
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
Supplemental hazard information (EU):	-
2.3	Other hazards
	-

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- xxxx	≥ 70 %	ethanol	Flam. Liq. 2; H225

SECTION 4. First aid measures	
4.1	Description of first aid measures
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.

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	Following ingestion:	Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Formation of toxic gases is possible during heating or in case of fire.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.

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	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.

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

SECTION 8. Exposure controls/personal protection				
8.1	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Ethanol	64-17-5	1000/-	1900/-	-
Substance name:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)
PNEC				

Trading name:	DIFFERENTIATING REAGENT FOR GIEMSA HP KIT			
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Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	no information available

8.2 Exposure controls

8.2.1. Appropriate engineering controls

Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
Structural measures to prevent exposure:	In accordance with Section 7.
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2. Skin protection	
Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.

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8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour:	alcohol like	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	17 °C	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	1 g/l (20°C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available

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	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	-		

SECTION 10. Stability and reactivity		
10.1	Reactivity:	See subsections 10.3 through 10.5.
10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3	Possibility of hazardous reactions:	No dangerous reactions known.
10.4	Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

SECTION 11. Toxicological information					
11.1	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	-	-	-	-
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	20.000 mg/l
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
	Aspiration hazard:		No information available.		
	Irritation and corrosion				
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-

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Serious eye damage/irritation	-	-	-	-	-
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Sensitization

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

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

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

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Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-
	Specific target organ toxicity – repeated exposure (STOT RE):					
	Specific effects			Target organ		Note
Subacute oral	No information available			No information available		-
Subacute dermal	No information available			No information available		-
Subacute inhalation	No information available			No information available		-
Subchronic oral	No information available			No information available		-
Subchronic dermal	No information available			No information available		-
Subchronic inhalation	No information available			No information available		-
Chronic oral	No information available			No information available		-
Chronic dermal	No information available			No information available		-
Chronic inhalation	No information available			No information available		-
	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)					
	Carcinogenicity:		Based on available data, the classification criteria are not met.			
	Mutagenicity <i>in vitro</i> :		Based on available data, the classification criteria are not met.			
	Genotoxicity:		Based on available data, the classification criteria are not met.			
	Mutagenicity <i>in vivo</i> :		Based on available data, the classification criteria are not met.			
	Germ cell mutagenicity:		Based on available data, the classification criteria are not met.			
	Reproductive toxicity:		Based on available data, the classification criteria are not met.			
	Summary of evaluation of the CMR properties:		Based on available data, the classification criteria are not met.			
11.2	Practical experiences:					
	Classification observations:		No information available			
	Other observations:		No information available			
11.3	General notes:					
	-					

SECTION 12. Ecological information	
12.1	Toxicity

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Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	4 days	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

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

Biodegradation

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

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12.3	Bioaccumulative potential						
	Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note	
-	-	-	-	-	-	-	
	Bioconcentration factor (BCF)						
Value	Species		Method		Evaluation	Note	
No information available	No information available	information available	No information available		No information available	-	
	Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note	
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-	
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-	
12.4	Mobility in soil						
	Known or predicted distribution in environmental compartments:						
	No information available						
	Surface tension:						
	Value	°C	Concentration	Method	Note		
	No information available	No information available	No information available	No information available	-		

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

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

No further relevant information available.

SECTION 13. Disposal considerations

13.1 Waste treatment methods

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.

13.1.6. Relevant Community provisions:

Disposal must be made according to official regulations.

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SECTION 14 TRANSPORT INFORMATION	
Transporting/shipment by road (ADR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3

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Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

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

SECTION 16. Other information		
16.1	Indication of changes:	-

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16.2	Abbreviations and acronyms:	PBT	Stable, bioaccumulative and toxic
		vPvB	Strongly stable and strongly bioaccumulative.
		LD ₅₀	Lethal dose, 50%
		LC ₅₀	Lethal concentration, 50%
		TCOJ	Specific target organ toxicity - single exposure
16.3.	Key literature references and source of data:	-	
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		
	H:	H225	Highly flammable liquid and vapor.
16.6.	Training advice:	-	
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.	

ANNEX: Exposure scenario resulting to chemical safety assessment
-

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Trading name:	DEHYDRATING REAGENT				
Product code:	RDH-OT-X**	Revision date:	12 July 2019	Version:	3

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

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

Trading name:	DEHYDRATING REAGENT			
Product code:	RDH-OT-X**	Revision date:	12 July 2019	Version: 3

Hazard pictograms:	
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
Supplemental hazard information (EU):	-
2.3	Other hazards
	-

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- xxxx	≥ 70 %	ethanol	Flam. Liq. 2; H225

SECTION 4. First aid measures	
4.1	Description of first aid measures
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.

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Product code:	RDH-OT-X**	Revision date:	12 July 2019	Version:	3

	Following ingestion:	Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Formation of toxic gases is possible during heating or in case of fire.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.

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	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.

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

SECTION 8. Exposure controls/personal protection				
8.1	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Ethanol	64-17-5	1000/-	1900/-	-
Substance name:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)
PNEC				

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Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	no information available

8.2 Exposure controls

8.2.1. Appropriate engineering controls

Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
Structural measures to prevent exposure:	In accordance with Section 7.
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2. Skin protection	
Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.

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8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour:	alcohol like	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	17 °C	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	1 g/l (20°C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available

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	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	-		

SECTION 10. Stability and reactivity		
10.1	Reactivity:	See subsections 10.3 through 10.5.
10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3	Possibility of hazardous reactions:	No dangerous reactions known.
10.4	Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

SECTION 11. Toxicological information						
11.1	Information on toxicological effects					
	Acute toxicity:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results	
Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg	
Dermal:	-	-	-	-	-	
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	20.000 mg/l	
	Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects		Target organ		Note	
Oral:	No information available		No information available		-	
Dermal:	No information available		No information available		-	
Inhalation:	No information available		No information available		-	
	Aspiration hazard:		No information available.			
	Irritation and corrosion					
	Exposure time		Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-	-

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Serious eye damage/irritation	-	-	-	-	-
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Sensitization

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

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

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

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Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-
	Specific target organ toxicity – repeated exposure (STOT RE):					
	Specific effects			Target organ		Note
Subacute oral	No information available			No information available		-
Subacute dermal	No information available			No information available		-
Subacute inhalation	No information available			No information available		-
Subchronic oral	No information available			No information available		-
Subchronic dermal	No information available			No information available		-
Subchronic inhalation	No information available			No information available		-
Chronic oral	No information available			No information available		-
Chronic dermal	No information available			No information available		-
Chronic inhalation	No information available			No information available		-
	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)					
	Carcinogenicity:		Based on available data, the classification criteria are not met.			
	Mutagenicity <i>in vitro</i> :		Based on available data, the classification criteria are not met.			
	Genotoxicity:		Based on available data, the classification criteria are not met.			
	Mutagenicity <i>in vivo</i> :		Based on available data, the classification criteria are not met.			
	Germ cell mutagenicity:		Based on available data, the classification criteria are not met.			
	Reproductive toxicity:		Based on available data, the classification criteria are not met.			
	Summary of evaluation of the CMR properties:		Based on available data, the classification criteria are not met.			
11.2	Practical experiences:					
	Classification observations:		No information available			
	Other observations:		No information available			
11.3	General notes:					
	-					

SECTION 12. Ecological information	
12.1	Toxicity

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Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	4 days	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

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

Biodegradation

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

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12.3	Bioaccumulative potential						
	Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note	
-	-	-	-	-	-	-	
	Bioconcentration factor (BCF)						
Value	Species		Method		Evaluation	Note	
No information available	No information available	information available	No information available		No information available	-	
	Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note	
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-	
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-	
12.4	Mobility in soil						
	Known or predicted distribution in environmental compartments:						
	No information available						
	Surface tension:						
	Value	°C	Concentration	Method	Note		
	No information available	No information available	No information available	No information available	-		

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

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

No further relevant information available.

SECTION 13. Disposal considerations

13.1 Waste treatment methods

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.

13.1.6. Relevant Community provisions:

Disposal must be made according to official regulations.

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SECTION 14 TRANSPORT INFORMATION	
Transporting/shipment by road (ADR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3

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Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

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

SECTION 16. Other information		
16.1	Indication of changes:	-

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16.2	Abbreviations and acronyms:	PBT	Stable, bioaccumulative and toxic
		vPvB	Strongly stable and strongly bioaccumulative.
		LD ₅₀	Lethal dose, 50%
		LC ₅₀	Lethal concentration, 50%
		TCOJ	Specific target organ toxicity - single exposure
16.3.	Key literature references and source of data:	-	
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		
	H:	H225	Highly flammable liquid and vapor.
16.6.	Training advice:	-	
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.	

ANNEX: Exposure scenario resulting to chemical safety assessment
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