

Trading name:	BOUIN'S SOLUTION				
Product code:	BOU-OT-X**	Revision date:	24.05.2019.	Version:	6

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1.	Product identifier	
	Trading name:	BOUIN'S SOLUTION
	Chemical name:	-
	Catalogue number:	BOU-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Fixative for use 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
	Fax no.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2 HAZARDS INFORMATION		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to (EC) Regulation No. 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Acute Tox. 4	H302
	Acute Tox. 4	H312
	Skin Irrit. 2	H315
	Skin. Sens. 1	H317
	Eye Irrit. 2	H319
	Acute Tox. 4	H332
	Carc. 2	H351
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		

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2.2.	Label 1272/2008 (CLP)	
	Product identification:	BOUIN'S SOLUTION
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	  GHS07GHS08
	Signal word:	Danger
	Hazard statements:	H302 Harmful if swallowed. H312 Harmful in contact with skin H315 Causes skin irritation H317 May cause an allergic skin reaction. H319 Causes serious eye irritation H332 Harmful if inhaled. H351 Suspected of causing cancer
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P301+P330+P331 IF SWALLOWED: rinse mouth. DO NOT induce vomiting. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/attention.
	Further information:	-
2.3.	Other hazards	
	-	

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
CAS/ EC/ Index no.	REACH Registration No	Mass %	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)

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50-00-0/ 200-001-8/ 605-001-00-5	01-2119488953- 20-XXXX	< 10%	formaldehyde, 37%	Acute Tox. 3; H301 Acute Tox. 3; H311 Skin Corr. 1B; H314 Derm. Sens. 1; H317 Acute Tox. 3; H331 Mutagenicity 2; H341 Carc. 1B; H350
64-19-7/ 200-580-7/ 607-002-00-6	-	< 5 %	acetic acid, glacial	Flam. Liq. 3; H226 Skin Corr. 1A; H314
88-89-1/ 201-865-9/ 609-009-00-X	-	< 2 %	picric acid	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331

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:	Remove person to fresh air. If breathing stops, immediately apply artificial respiration. If breathing difficulties occur, use emergency breathing apparatus. If the symptoms persist, immediately consult a physician.
	Following skin contact:	Take off immediately all contaminated clothing. Immediately 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 the oral cavity; drink at most 1-2 glasses of water. Do not induce vomiting. 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:	Irritation of the mucous membrane of the nose/throat may occur (burning sensation, urge to sneeze, runny nose). High concentration may cause difficult breathing, coughing fits, chest tightness, headache, vertigo and drowsiness.
	Following skin contact:	Irritation, redness with stinging and pain, skin cracking, rash, swelling, burns, blisters and delayed onset of inflammatory processes may occur.

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	Following eye contact:	Depending on concentration and exposure time, mucosa stinging, lacrimation, redness and pain may occur, as well as bleeding, delayed onset of inflammatory processes and permanent eyesight damage.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting (possibly of bloody content).
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5 Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Possible liberation of toxic carbon monoxide and formaldehyde gases due to thermal decomposition (increased temperature). Explosive mixtures of formaldehyde vapors and air also present danger.
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray, in order to prevent explosion.	
5.4.	Additional information	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

SECTION 6 ACCIDENTAL RELEASE MEASURES		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	

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

SECTION 7 HANDLING AN 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 heat and ignition. Carry out measures for preventing static electricity.
	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.

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	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 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	
Formaldehyde	50-00-0	2	2.5	-
Acetic acid, glacial	64-19-7	10	25	-
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	1 mg/m ³ (formaldehyde)	-	0.5 mg/m ³ (formaldehyde)	9 mg/m ³ (formaldehyde)
Dermal	-	-	0.037 mg/cm ² (formaldehyde)	-
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	4.1 mg/kg (formaldehyde)
Inhalation	-	-	0.1 mg/m ³ (formaldehyde)	3.2 mg/m ³ (formaldehyde)

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

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

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

8.2.2. Personal protection equipment

8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the EU Directive 89/686/EEC and standard EN 374. Full contact: Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min Splash contact: Gloves material: polychloroprene Glove thickness: 0.65 mm Time until perforation: >240 min

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	Other skin protection:	Wear protective suit with long sleeves (EN 340) that protects from chemicals and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Full face mask (EN 136) or half mask (EN 140) equipped with a recommended "ABEK" filter (EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Color:	yellow	No information available
	Odor:	pungent	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point;	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapor pressure:	No information available	No information available
	Vapor density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available

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	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
	Oxidizing properties:	No information available	No information available
9.2.	Other information		
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SECTION 10 STABILITY AND REACTIVITY		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	No information available
10.4.	Conditions to avoid:	Sources of heat, sparks, ignition, and low temperature.
10.5.	Incompatible materials:	Highly oxidizing agents, acids, bases and different metals, steel manufactured by melting, copper.
10.6.	Hazardous decomposition products:	Carbon monoxides.

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 exposure:	No information available	rat	LD ₅₀	No information available	>200 mg/kg (formaldehyde)
Dermal exposure:	No information available	rabbit	LD ₅₀	No information available	>270 mg/kg (formaldehyde)
Inhalation exposure:	No information available	rat	LC ₅₀	4 h	0.58 mg/l (formaldehyde)
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects			Target organ	Note
Oral exposure:	No information available			-	-
Dermal exposure:	No information available			-	-
Inhalation exposure:	No information available			-	-

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Aspiration hazard:		possible respiratory system irritation.				
Irritation and corrosion						
Exposure time		Species	Evaluation	Method	Note	
Skin corrosion/irritation	No information available	-	-	-	Causes skin irritation.	
Serious irritation to eyes:	No information available	-	-	-	Causes serious eye irritation.	
Sensitization						
Dermal exposure:		May cause allergic skin reaction.				
Inhalation exposure:		Allergic persons may display irritation.				
Symptoms related to the physical, chemical and toxicological characteristics						
Oral exposure:		If swallowed it can cause severe burns to mouth and throat, and danger of esophagus and stomach perforation.				
Dermal exposure:		Depending on concentration and exposure time, redness accompanied by sensation of stinging and pain may occur, as well as burns and blistering.				
Inhalation exposure:		Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and shortness of breath. Inhalation may cause formation of oedema in respiratory tract and may cause damage.				
Eye exposure:		Causes serious eye damage. Fumes may cause lacrimal irritation (tearing), blindness hazard.				
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	No information available
Subacute dermal	No information available	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	No information available
Subchronic oral	No information available	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	No information available
Subchronic inhalation	No information available	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	No information available
Chronic dermal	No information available	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	No information available

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

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

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)

Carcinogenicity:	Based on IARC tests conducted on rats, tumors appeared in nose and in pharynx. Other organisms do not yield positive results. If the operator adheres to the personal hygiene rules and uses personal protection listed in the exposure scenario, those hazards are non-existent.
Mutagenicity <i>in vitro</i> :	No information available.
Genotoxicity:	No information available.
Mutagenicity <i>in vivo</i> :	No information available.
Germ cell mutagenicity:	No information available.
Reproductive toxicity:	No information available.

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	Summary of evaluation of the CMR properties:	No information available.
11.2.	Practical experiences:	
	Remarks relevant for classification:	No information available
	Other remarks:	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>Pimephales promelas</i>	-	24.1 – 41 mg/l (formaldehyde)	-
Crustacea:	EC ₅₀	48 hours	water flea (<i>Daphnia magna</i>)	-	2 mg/l (formaldehyde)	-
Algae/aquatic plants	IC ₅₀	72 hours	algae	-	2. 5 mg/l (formaldehyde)	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	No information available	-
Crustacea:	EC ₅₀	48 hours	-	-	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	-	-	No information available	-
Other organisms	-	-	-	-	No information available	-
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
No information available	No information available	No information available	No information available	-

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

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

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:

Surface tension:

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

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

12.5.	Results of PBT and vPvB assessment
	No information available
12.6.	Other adverse effects
	No information available

SECTION 13 DISPOSAL CONSIDERATIONS	
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.

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13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.
13.1.6.	Relevant Community provisions:
	-

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
UN number:	Not subject to marking 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 marking 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 marking 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 marking regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II	-

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of MARPOL 73/78 and the IBC code:	
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	3334
UN proper shipping name:	Aviation regulated liquid, n.o.s. (formaldehyde)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	None
Special precautions for user:	-
Further information: Formaldehyde solutions, nonflammable, containing less than 25% of formaldehyde do not adhere to the ADR regulations.	

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	

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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 STOT - RE Specific target organ toxicity - repeated 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 according to CLP	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H:	H226 Flammable liquid and vapor. H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled. H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled . H314 Causes severe skin burns and eye damage H315 Causes skin irritation. H317 May cause allergic skin reaction. H319 Causes serious eye irritation H341 Suspected of causing genetic defects. H350 May cause cancer. H351 Suspected of causing cancer.
16.6.	Training advice:	-
16.7.	Further information:	"X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT
-

Trade name:	HEMATOXYLIN, WEIGERT A				
Product code:	HEMA-OT-X**	Date of compilation:	03 June 2019	Version:	4

SECTION 1. Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	HEMATOXYLIN, WEIGERT A
	Chemical name:	-
	Catalogue number:	HEMA-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in Hematoxylin W 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
	Skin. Sens. 1	H317
	Canc. 2	H351
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	HEMATOXYLIN, WEIGERT A
	Identification number:	-

Trade name:	HEMATOXYLIN, WEIGERT A				
Product code:	HEMA-OT-X**	Date of compilation:	03 June 2019	Version:	4

Authorisation number:	-
Hazard pictograms:	 GHS02  GHS07  GHS08
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor. H317 May cause an allergic skin reaction. H351 Suspected of causing cancer.
Precautionary statement:	P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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 (REGULATION) (EC) No 1272/2008 (CLP)
107-21-1/ 203-473-3/ 603-027-00-1	01-2119456816- 28-xxxx	< 10	ethylene glycol	Acute Tox. 4, H302

Trade name:	HEMATOXYLIN, WEIGERT A				
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64-17-5/ 200-578-6/ 603-002-00-5 121-79-9/ 204-498-2/ 607-198-00-3 123-31-9/ 204-617-8/ 604-005-00-4	01-2119457610- 43-xxxx	≥ 50	ethanol	Flam. Liq. 2, H225
	-	< 3	propyl gallate	Acute Tox. 4, H302 Skin Sens. 1 H317
	-	< 5	hydroquinone	Acute Tox. 4; H302 Canc. 2; H351 Eye Dam. 1; H318 Skin Sens. 1; H317 Aquatic Acute 1; H400 Muta. 2; H341

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. Thoroughly wash with water for 15 minutes.
	Following eye contact:	Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open.
	Following ingestion:	Rinse the mouth thoroughly with water. If the afflicted person is conscious, provide them with large amounts of water. Consult a physician.
	Self-protection of the first aider	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	May cause eye irritation and upper respiratory system (stinging sensation, irritation). Bronchoconstriction is possible. Possible symptoms include CNS symptoms such as headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration.
	Following skin contact:	Defatting, dry skin.
	Following eye contact:	Splatter may cause discomfort, stinging sensation, conjunctival redness, corneal surface lesions.
	Following ingestion:	It may lead to occurrence of strong sensation of stinging, headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration. If denaturants are present, dyspepsia may occur (such as vomiting).
4.3.	Indication of any immediate medical attention and special treatment needed	

Trade name:	HEMATOXYLIN, WEIGERT A				
Product code:	HEMA-OT-X**	Date of compilation:	03 June 2019	Version:	4

No information available

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, alcohol-resistant foam, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	Water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Incomplete combustion of the product.
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
5.4.	Additional information	
	-	

SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus.
	Accident prevention methods:	Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks.
	Emergency procedures:	Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection.
6.1.2.	For emergency responders:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and 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:	Sawdust, sand, mineral adsorbents

Trade name:	HEMATOXYLIN, WEIGERT A				
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6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112).
6.4.	Reference to other sections	
	-	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use tools that cause sparks.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in a well-ventilated place. Keep away from heat and direct solar radiation.
	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:	-
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/-	-
Ethylene glycol	107-21-1	20/40	52/104	-

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Hydroquinone	123-31-9	-/05	-/-	-
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Substance:	-
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EC No:	-	CAS No:	-
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DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	35 mg/ kg (ethylene glycol)	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol) 106 mg/kg (ethylene glycol)

Critical physical parameters: solubility, flammability, corrosivity:

Consumer

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

PNEC

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

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8.2.	Exposure controls	
8.2.1.	Engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	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:	See Section 7.2
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	In case of coming into thorough contact, use butyl rubber gloves (0.4 mm thick). In case of contact with drops, use polychlorene gloves (0.1 mm thick). Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374.
	Other skin protection:	During everyday work use cotton clothing and suitable footwear, such as rubber boots or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values, use full gas mask equipped with brown filter A.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties	
9.1.	Information on basic physical and chemical properties

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	Value	Method
Physical state:	liquid	No information available
Colour:	brown	No information available
Odour:	ethanol like	No information available
Odour threshold;	No information available	No information available
pH:	No information available	No information available
Melting point / freezing point;	No information available	No information available
Initial boiling point and boiling range:	No information available	No information available
Flash point:	20°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):	Completely soluble in water	No information available
Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
Viscosity:	No information available	No information available
Explosive properties:	No information available	No information available
Oxidising properties:	No information available	No information available
9.2.	Other information	
	-	

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	The product is stable under normal working and storage conditions.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.
10.4.	Conditions to avoid:	High temperatures, ignition sources, open flame.
10.5.	Incompatible materials:	Oxidants, acids, alkali metals.

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10.6.	Hazardous decomposition products:	Non-degradable if used in the described manner.
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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	-	7.060 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol)
Dermal:	No information available	rabbit	LD ₅₀	-	>3.500mg/kg (ethylene glycol)
Inhalation:	No information available	rat	LC ₅₀	4 h (ethanol)	20.000 mg/l (ethanol)
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
	Respiratory irritation:		May cause respiratory irritation.		
	Irritation and corrosion				
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	No information available
Serious eye damage/irritation	-	-	-	-	No information available
	Sensitization:				
Skin sensitization:	No information available				
Respiratory sensitization:	No information available				
	Symptoms related to the physical, chemical and toxicological characteristics				
Oral exposure:	It may lead to occurrence of strong sensation of stinging, headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration. If denaturants are present, dyspepsia may occur (such as vomiting).				

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Dermal exposure:	Defatting, dry skin.
Inhalation exposure:	May cause eye irritation and upper respiratory system (stinging sensation, irritation). Bronchoconstriction is possible. Possible symptoms include CNS symptoms such as headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration.
Eye exposure:	Splatter may cause discomfort, stinging sensation, conjunctival redness, corneal surface lesions.

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

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

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

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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:	-		

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

SECTION 12. Ecological information:						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Fish	No information available	72.860 mg/l (ethylene glycol)	-
Crustacea:	EC ₅₀	48 hours	water flea	No information available	>100 mg/l (ethylene glycol)	-

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Algae/aquatic plants	IC ₅₀	72 hours	algae	No information available	6.500-13.000 mg/l (ethylene glycol)	-
Microorganisms	-	-	No information available	No information available	No information available	-
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	-
Microorganisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

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

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
-	-	-	-	-

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

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

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

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

12.4. Mobility in soil

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

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

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Soil-air	No information available	No information available	No information available	No information available	-
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12.5.	Results of PBT and vPvB assessment
	No information available

12.6.	Other adverse effects
	No information available

SECTION 13. Disposal considerations

13.1.	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

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

13.1.3.	Waste treatment – relevant information:
	No information available

13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.

13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.

13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3

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Packing group:	II
Environmental hazards:	No information available
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
Special precautions for user:	-
Further information:	
-	

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15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	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, 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 vPvB LD ₅₀ LC ₅₀ TCOJ	Stable, bioaccumulative and toxic Strongly stable and strongly bioaccumulative. Lethal dose, 50% Lethal concentration, 50% Specific target organ toxicity - single exposure	
16.3.	Key literature references and source of data:		-	
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classification		Classification procedure		

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-	-
16.5.	Relevant H statements (number and full text)
H:	225 302 317 318 341 351 400 Highly flammable liquid and vapor. Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye damage. Suspected of causing genetic defects. May cause cancer. Very toxic to aquatic life.
16.6.	Training advice:
	-
16.7.	Further information:
	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT
-

Trading name:	FERRI REAGENT, WEIGERT B				
Product code:	FR-OT-X**	Revision date:	03 June 2019	Version:	4

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1.	Product identifier	
	Trading name:	FERRI REAGENT, WEIGERT B
	Chemical name:	-
	Catalogue number:	FR-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in Hematoxylin W 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
	Fax no.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2 HAZARDS INFORMATION		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification (REGULATION (EC) No. 1272/2008 (CLP))	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Classification according to EC Directive Nr. 1272/2008 CLP)	
	Product identification:	FERRI REAGENT, WEIGERT B
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	-
	Signal word:	-

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

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
7782-61-8/ 616-509-1/ -	-	< 0.5%	ferric nitrate nonahydrate	Skin Irrit. 2; H315 Eye Irrit. 2; H319
7647-01-0/ 231-595-7/ 017-002-00-2	01-2119484862- 27-xxxx	< 1%	hydrochloric acid, 37%	Skin Corr. 1A; H314 Acute Tox. 3; H331

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

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

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

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

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Product code:	FR-OT-X**	Revision date:	03 June 2019	Version:	4

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

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

Trading name:	FERRI REAGENT, WEIGERT B				
Product code:	FR-OT-X**	Revision date:	03 June 2019	Version:	4

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	
Hydrogen chloride		7647-01-0	5/10	8/15	-
Substance name:	-				
EC No:	-	CAS No:	-		
DNEL					
Industrial					
Route of exposure:	Acute effect local	Acute effect systemic		Chronic effect local	Chronic effect systemic
Oral	-	-		-	-
Inhalation	-	-		-	-
Dermal	-	-		-	-
Critical physical parameters: solubility, flammability, corrosivity:				-	
Consumer					
Route of exposure:	Acute effect local	Acute effect systemic		Chronic effect local	Chronic effect systemic
Oral	-	-		-	-
Inhalation	-	-		-	-
Dermal	-	-		-	-
PNEC					
Environmental protection target			PNEC		
Fresh water			No information available		
Freshwater sediments			No information available		
Marine water			No information available		
Marine sediments			No information available		
Food chain			No information available		
Microorganisms in sewage treatment			No information available		
Soil (agricultural)			No information available		
Air			No information available		
8.2.	Exposure controls				

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Product code:	FR-OT-X**	Revision date:	03 June 2019	Version: 4

8.2.1.	Engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Color:	pale yellow	No information available

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

SECTION 10 STABILITY AND REACTIVITY		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	With strong oxidants, sodium-hydroxide, sulfuric acid, aluminum.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Aluminum.
10.6.	Hazardous decomposition products:	No information available.

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

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Product code:	FR-OT-X**	Revision date:	03 June 2019	Version:	4

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

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

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

Respiratory irritation: No information available

Irritation and corrosion

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

Sensitization

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

Symptoms related to the physical, chemical and toxicological characteristics

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

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Repeated dose toxicity (subacute, subchronic, chronic)						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Specific target organ toxicity – repeated exposure (STOT RE):						
	Specific effects		Target organ		Note	
Subacute oral	No information available		No information available		-	
Subacute dermal	No information available		No information available		-	
Subacute inhalation	No information available		No information available		-	
Subchronic oral	No information available		No information available		-	
Subchronic dermal	No information available		No information available		-	
Subchronic inhalation	No information available		No information available		-	
Chronic oral	No information available		No information available		-	

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Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-
	CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)		
	Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.	
	Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.	
	Genotoxicity:	No information available	
	Mutagenicity <i>in-vivo</i> :	Current <i>in vivo</i> tests did not indicate mutagenic effects.	
	Germ cell mutagenicity:	No information available	
	Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.	
	Summary of evaluation of the CMR properties:	-	
11.2.	Practical experiences:		
	Remarks relevant for classification:	No information available	
	Other remarks:	No information available	
11.3.	General notes:		
	-		

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

Trading name:	FERRI REAGENT, WEIGERT B				
Product code:	FR-OT-X**	Revision date:	03 June 2019	Version:	4

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

12.2. Persistence and degradability

Abiotic degradation

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

Biodegradation

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

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log K_{ow}):

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

Bioconcentration factor (BCF)

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

Trading name:	FERRI REAGENT, WEIGERT B				
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Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

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

Adsorption / desorption

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

12.5. Results of PBT and vPvB assessment

No information available

12.6. Other adverse effects

No information available

Trading name:	FERRI REAGENT, WEIGERT B				
Product code:	FR-OT-X**	Revision date:	03 June 2019	Version:	4

SECTION 13 DISPOSAL CONSIDERATIONS	
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-
SECTION 14 TRANSPORT INFORMATION	
Transporting/shipment by road (ADR)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-

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Product code:	FR-OT-X**	Revision date:	03 June 2019	Version:	4

Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

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

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

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

Further information:	The product is not subject to classification.
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SECTION 15 REGULATORY INFORMATION	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -

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

SECTION 16 Other information					
16.1.	Indication of changes: -				
16.2.	<table> <tr> <td>Abbreviations and acronyms:</td><td> PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity - single exposure </td></tr> </table>	Abbreviations and acronyms:	PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD ₅₀ Lethal dose, 50% LC ₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity - single exposure		
Abbreviations and acronyms:	PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD ₅₀ Lethal dose, 50% LC ₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity - single exposure				
16.3.	Key literature references and source of data: -				
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
<table> <tr> <td>Classification</td><td>Classification procedure</td></tr> <tr> <td>-</td><td>-</td></tr> </table>		Classification	Classification procedure	-	-
Classification	Classification procedure				
-	-				
16.5.	Relevant H statements (number and full text)				

Trading name:	FERRI REAGENT, WEIGERT B				
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	H:	H314 H315 H319 H331	Causes severe skin burns and eye damage. Causes skin irritation. Causes serious eye irritation. Toxic if inhaled.
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:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT
	Chemical name:	-
	Catalogue number:	CABR-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Blue counterstain used with Gomori Trichrome 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*:
	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:	CHROMOTROPE 2R / ANILINE BLUE REAGENT
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	-

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

	Signal word:	-
	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 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:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

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, dry powder, CO ₂ or alcohol resistant foam
	Unsuitable extinguishing media: Water with full jet
5.2	Special hazards arising from the substance or mixture
	Hazardous combustion products: 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
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.

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

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

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.
	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

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

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

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

	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.
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

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

		Value	Method
	Physical state:	liquid	No information available
	Colour:	purple - blue	No information available
	Odour:	No information available	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	-		

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 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

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT				
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SECTION 11. Toxicological information					
11.1	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	No information available	-	No information available	-	-
Dermal:	No information available	-	No information available	-	-
Inhalation:	No information available	-	No information available	-	-
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
	Aspiration hazard:		No information available.		
	Irritation and corrosion				
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-
	Sensitization				
Skin sensitization:		No information available.			
Respiratory sensitization:		No information available.			
	Symptoms related to the physical, chemical and toxicological characteristics				
Oral exposure:		Harmful if swallowed.			
Dermal exposure:		Harmful if absorbed through skin. May cause skin irritation.			
Inhalation exposure:		Harmful if inhaled. May cause respiratory tract irritation.			
Eye exposure:		May cause eye irritation.			

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Repeated dose toxicity (subacute, subchronic, chronic)						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Specific target organ toxicity – repeated exposure (STOT RE):						
	Specific effects		Target organ		Note	
Subacute oral	No information available		No information available		-	
Subacute dermal	No information available		No information available		-	
Subacute inhalation	No information available		No information available		-	
Subchronic oral	No information available		No information available		-	
Subchronic dermal	No information available		No information available		-	
Subchronic inhalation	No information available		No information available		-	
Chronic oral	No information available		No information available		-	
Chronic dermal	No information available		No information available		-	

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT				
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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					
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	-

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT				
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version:	3

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

12.2 Persistence and degradability

Abiotic degradation

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

Biodegradation

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

12.3 Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

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

Bioconcentration factor (BCF)

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

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT				
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Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-
12.4	Mobility in soil					
	Known or predicted distribution in environmental compartments:					
	No information available					
	Surface tension:					
	Value	°C	Concentration	Method	Note	
	No information available	No information available	No information available	No information available	-	
	Adsorption / desorption					
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	No information available	-
Water-air	No information available	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	No information available	-
12.5	Results of PBT and vPvB assessment					
	Not applicable.					
12.6	Other adverse effects					
	No further relevant information available.					

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

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:
	15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.
13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.
SECTION 14 TRANSPORT INFORMATION	
	Transporting/shipment by road (ADR)
UN number:	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:	-

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

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

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT			
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version: 3

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:		-	
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:		-	

Trading name:	CHROMOTROPE 2R / ANILINE BLUE REAGENT				
Product code:	CABR-OT-X**	Date of compilation:	27 June 2019	Version:	3

16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.
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ANNEX: Exposure scenario resulting to chemical safety assessment
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Trading name:	REAGENT FOR DIFFERENTIATION IN GOMORI TRICHROME KIT				
Product code:	RDG-OT-X**	Date of compilation:	27 June 2019	Version:	3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	REAGENT FOR DIFFERENTIATION IN GOMORI TRICHROME KIT
	Chemical name:	-
	Catalogue number:	RDG-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with special staining kits.
	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:	REAGENT FOR DIFFERENTIATION IN GOMORI TRICHROME KIT
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	-

Trading name:	REAGENT FOR DIFFERENTIATION IN GOMORI TRICHROME KIT				
Product code:	RDG-OT-X**	Date of compilation:	27 June 2019	Version:	3

	Signal word:	-
	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)
64-19-7/ 200-580-7/ 607-002-00-6	-	< 1%	acetic acid, glacial 99%	Flam. Liquid 3; H226 Skin Corr. 1A; H314

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

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	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
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, dry powder, CO ₂ or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	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	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.	

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

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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.
	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).

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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:	-
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EC No:	-	CAS No:	-
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DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity:	-
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Consumer

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

PNEC

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

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

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Technical measures to prevent exposure:	See Section 6
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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:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	-		

SECTION 10. Stability and reactivity		
10.1	Reactivity:	See subsections 10.3 through 10.5.

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

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Symptoms related to the physical, chemical and toxicological characteristics						
Oral exposure:		Harmful if swallowed.				
Dermal exposure:		Harmful if absorbed through skin. May cause skin irritation.				
Inhalation exposure:		Harmful if inhaled. May cause respiratory tract irritation.				
Eye exposure:		May cause eye irritation.				
Repeated dose toxicity (subacute, subchronic, chronic)						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Specific target organ toxicity – repeated exposure (STOT RE):						
	Specific effects			Target organ		Note
Subacute oral		No information available		No information available		-
Subacute dermal		No information available		No information available		-

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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					
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	-

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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

12.3 Bioaccumulative potential

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

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

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

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

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

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

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Soil-air	No information available	No information available	No information available	No information available	-
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12.5	Results of PBT and vPvB assessment
	Not applicable.

12.6	Other adverse effects
	No further relevant information available.

SECTION 13. Disposal considerations

13.1	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2.	Waste codes/waste designations according to Law:
	15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3.	Waste treatment – relevant information:
	No information available

13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.

13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.

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

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-

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

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SECTION 15. Regulatory information		
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	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:	-
16.2	Abbreviations and acronyms:	PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% TCOJ Specific target organ toxicity - single exposure
16.3.	Key literature references and source of data:	-

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16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		
	H:	H226 H314	Flammable liquid and vapour. Causes severe skin burns and eye damage.
16.6.	Training advice:		-
16.7.	Further information:		** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to chemical safety assessment					
-					