

## CONGO RED HIGHMAN KIT

The kit contains:

Congo Red reagent

Hematoxylin G2



Potassium hydroxide, solution

Trading name:	<b>CONGO RED REAGENT</b>			
Product code:	CR-OT-X**	Date of compilation:	21 Dec 2022	Version: 5

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	CONGO RED REAGENT
	Chemical name:	-
	Catalogue number:	CR-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Congo Red Highman 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:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	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. 3	H226
	Carc. 1B	H350
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	CONGO RED REAGENT
	Identification number:	-
	Authorization number:	-

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Hazard pictograms:	 
	GHS02                      GHS08
Signal word:	Danger
Hazard statements:	H226 Flammable liquid and vapour. H350 May cause cancer.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/face protection. P308+P313 If exposed or concerned: Get medical advice/attention.
Supplemental hazard information (EU):	-

2.3	Other hazards
	<p><b>Endocrine Disrupting Properties:</b>  No known endocrine disrupting properties</p> <p><b>Results of PBT and vPvB assessment:</b> According to the results of its assessment, this substance is not a PBT or a vPvB.</p> <p>(Direct Red 28 C.I.) Included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH).</p>

<b>SECTION 3. Composition/information on ingredients</b>				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01- 2119457610- 43-xxxx	40 - 60 %	ethanol	Flam. Liq. 2; H225
573-58-0/ 209-358-4/ 611-027-00-8	-	1 – 2 %	disodium 3,3'-[[1,1'-biphenyl]-4,4'- diylbis(azo)]bis(4- aminonaphthalene-1-sulphonate)	Carc. 1B; H350 Repr. 2; H361d

<b>SECTION 4. First aid measures</b>	
4.1	Description of first aid measures

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	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

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

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

<b>SECTION 7. Handling and storage</b>		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms.
	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.	

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7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage roomsat temperatures ranging from 15 to 25 °C.
	Packaging materials:	Manufacturer's original packaging. Avoid metal containers.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection					
8.1	Control parameters				
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values	
		ppm	mg/m <sup>3</sup>		
Ethanol	64-17-5	1000/-	1900/-	-	
Substance name:		-			
EC No:		-	CAS No:		-
DNEL					
Industrial					
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic	
Oral	-	-	-	-	
Inhalation	1900 mg/m <sup>3</sup> (ethanol)	-	-	380 mg/m <sup>3</sup> (ethanol)	
Dermal	-	-	-	343 mg/kg (ethanol)	
Critical physical parameters: solubility, flammability, corrosivity:			-		
Consumer					

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Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m <sup>3</sup> (ethanol)	-	-	114 mg/m <sup>3</sup> (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)

PNEC	
Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	2.9 mg/kg (ethanol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol)
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	No information available

8.2	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	Protective nitrile gloves, 0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.

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8.2.2.3.	Respiratory protection:	Suitable mask (EN 136) or half mask (EN 140) equipped with a combined "A1 + Form" filter (EN 143) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	<b>Environmental exposure controls</b>	
	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

<b>SECTION 9. Physical and chemical properties</b>			
9.1	<b>Information on basic physical and chemical properties</b>		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	red	No information available
	Odour/odour threshold:	biting/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	24 °C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available



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9.2	Other information
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SECTION 10. Stability and reactivity		
10.1	Reactivity:	The product is stable under normal working and storage conditions.
10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3	Possibility of hazardous reactions:	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 <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results
Oral:	No information available	rat	No information available	-	15.200 mg/kg (Direct Red 28)
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

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Skin corrosion/irritation:	No information available	No information available	No information available	No information available	-
Serious eye damage/irritation	No information available	No information available	No information available	No information available	-

<b>Sensitization</b>
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Skin sensitization:	No information available
Respiratory sensitization:	No information available

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>
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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).
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.

<b>Repeated dose toxicity (subacute, subchronic, chronic)</b>
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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	-

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

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

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)						
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	Carcinogenicity:	Presumed to have carcinogenic potential for humans.
	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:	Suspected of damaging the unborn child.

	Summary of evaluation of the CMR properties:	No information available
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11.2	Information on other hazards:
11.2.1.	Endocrine disrupting properties:

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

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	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 <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	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

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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	-		

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

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12.4 Mobility in soil						
	Known or predicted distribution in environmental compartments:					
	No information available					
	Surface tension:					
	Value	°C	Concentration	Method	Note	
	No information available	No information available	No information available	No information available	-	
	Adsorption / desorption					
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	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						
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.					
12.6. Endocrine disrupting properties						
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.					
12.7. Other adverse effects						
	No information available					
SECTION 13. Disposal considerations						

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13.1	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.
13.1.6.	Relevant Community provisions:
	-

#### SECTION 14 TRANSPORT INFORMATION

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

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

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



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

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

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16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
	Classification		Classification procedure		
	-		-		
16.5.	Relevant H statements (number and full text)				
	H:	225	Highly flammable liquid and vapour.		
		226	Flammable liquid and vapour.		
		350	May cause cancer.		
		361d	Suspected of damaging the unborn child.		
16.6.	Training advice:		-		
16.7.	Further information:		<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>		


<b>ANNEX: Exposure scenario resulting to chemical safety assessment</b>					
-					

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

<b>SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING</b>		
1.1.	Product identifier	
	Trading name:	HEMATOXYLIN G2
	Chemical name:	-
	Catalogue number:	HEMG2-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Hematoxylin according to Gill for nuclear staining.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Fax no.:	+385 1 2404039
	e-mail of competent person:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

<b>SECTION 2 HAZARDS INFORMATION</b>		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification (REGULATION (EC) No. 1272/2008 (CLP))	
	Hazard class and category code:	Hazard statements*:
	Acute Tox. 4	H302
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	HEMATOXYLIN G2
	Identification number:	-
	Authorization no.:	-

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

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
107-21-1/ 203-473-3/ 603-027-00-1	01-2119456816- 28-xxxx	25 - 45 %	ethylene glycol	Acute Tox. 4, H302

SECTION 4 FIRST AID MEASURES		
4.1.	<b>Description of first aid measures</b>	
	General notes:	-
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.

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	Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.
	Self-protection of the first aider:	Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation. If the symptoms persist, immediately call a physician.
	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

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

SECTION 6 ACCIDENTAL RELEASE MEASURES		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).

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	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Wear protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

<b>SECTION 7 HANDLING AND STORAGE</b>		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	

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

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION				
8.1.	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m³	
Ethylene glycol	107-21-1	20/40	52/104	No information available
Substance name:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	35 mg/ kg (ethylene glycol)	
Dermal	-	-	-	106 mg/kg (ethylene glycol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				

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

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

8.2.	Exposure controls	
8.2.1.	Engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.11 mm Break through time: >480 min



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	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	<b>Environmental exposure controls</b>	
	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

<b>SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES</b>			
9.1.	<b>Information on basic physical and chemical properties</b>		
		Value	Method
	Physical state:	liquid	No information available
	Color:	dark red	No information available
	Odour/odour threshold:	very mild vinegar odour/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available

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

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

SECTION 11 TOXICOLOGICAL INFORMATION					
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral exposure:	anhydrous (ECHA)	rabbit	LD <sub>50</sub>	-	7.712 mg/kg (ethylene glycol)
Dermal exposure:	anhydrous (ECHA)	rat	LD <sub>50</sub>	-	>3.500mg/kg (ethylene glycol)
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-	-
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral exposure:	No information available		No information available		-
Dermal exposure:	No information available		No information available		-
Inhalation exposure:	No information available		No information available		-
	Respiratory irritation:		No information available		
	Irritation and corrosion				
	Exposure time	Species	Evaluation	Method	Note

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

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

Symptoms related to the physical, chemical and toxicological characteristics
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Oral exposure:	No information available
Dermal exposure:	No information available
Inhalation exposure:	No information available
Eye exposure:	Causes serious eye damage

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	-

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

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.
Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	Current <i>in vivo</i> tests did not indicate mutagenic effects.
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.

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

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SECTION 12 ECOLOGICAL INFORMATION:						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	Fish	No information available	72.860 mg/l (ethylene glycol)	-
Crustacea:	EC <sub>50</sub>	48 hours	water flea	No information available	>100 mg/l (ethylene glycol)	-
Algae/aquatic plants	IC <sub>50</sub>	8 days	algae	No information available	6.500-13.000 mg/l (ethylene glycol)	-
Microorganisms	LC <sub>50</sub>	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
12.2.	Persistence and degradability					
	Abiotic degradation					
	Degradation half-lives		Method		Evaluation	Note
Marine water	No information available		No information available		No information available	-
Fresh water	No information available		No information available		No information available	-
Air	No information available		No information available		No information available	-
Soil	No information available		No information available		No information available	-
	Biodegradation					
% Degradation		Time (days)	Method		Evaluation	Note
No information available		No information available	No information available		No information available	No information available

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12.3.	Bioaccumulative potential
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	Partition coefficient: n-octanol/water (log Kow):
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Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

	Bioconcentration factor (BCF)
--	-------------------------------

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

	Chronic ecotoxicity
--	---------------------

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea ( <i>Daphnia</i> )	EC <sub>50</sub>	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	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					
	Based on available data, the product does not contain any PBT or vPvB substances.					
12.6.	Endocrine disrupting properties					
	No known endocrine disrupting properties that affect the environment.					
12.7.	Other adverse effects					
	No adverse effects are expected.					
<b>SECTION 13 DISPOSAL CONSIDERATIONS</b>						
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.					
13.1.2.	Waste codes/waste designations according to Law:					
	No information available					
13.1.3.	Waste treatment – relevant information:					
	No information available					
13.1.4.	Sewage disposal – relevant information:					
	Waste must not be disposed of into the sewage system.					

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

#### **SECTION 14 TRANSPORT INFORMATION**

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



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

<b>SECTION 15 REGULATORY INFORMATION</b>	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -
	<p>Other EU regulations:</p> <p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)

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	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment	
	None	

SECTION 16 Other information		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H: 302	Harmful if swallowed.
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:	<b>POTASSIUM HYDROXIDE, SOLUTION</b>			
Product code:	KHO-OT-X**	Date of compilation:	14 November 2022	Version: 5


### SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1.	Product identifier	
	Trading name:	POTASSIUM HYDROXIDE, SOLUTION
	Chemical name:	-
	Product code:	KHO-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 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:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

### SECTION 2. Hazards identification

2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statement*:
	Skin Irr. 2	H315
	Eye Irr. 2	H319
2.1.2.	Additional information	
	-	
*For the full text of H and EUH phrases see Section 16.		
2.2.	Label elements	
	Product identification:	POTASSIUM HYDROXIDE, SOLUTION
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	 GHS07
Signal word:	Warning
Hazard statement:	H315 Causes skin irritation H319 Causes serious eye irritation.
Precautionary statement:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. 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.
Supplemental hazard information (EU):	-
2.3.	Other hazards
	No known endocrine disrupting properties. This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 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)
1310-58-3 215-181-3 019-002-00-8	-	1 - 2 %	potassium hydroxide	Met. Corr. 1; H290 Ac. Tox. 4; H302 Skin Corr. 1A; H314

### SECTION 4. First aid measures

4.1.	Description of first aid measures
General notes:	Move out of dangerous area. Show this safety data sheet to the doctor and first responders.
Following inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Get medical advice.
Following skin contact:	Wash off with soap and plenty of water. If irritation occurs and persists: Get medical advice.

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	Following eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation occurs and persists: Get medical advice.
	Following ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water.
	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.
4.3.	Indication of any immediate medical attention and special treatment needed	
	Treat symptomatically.	

#### SECTION 5. Firefighting measures

5.1.	Extinguishing media	
	Suitable extinguishing media:	Use dry chemical, CO <sub>2</sub> , water spray (FOG) or foam.
	Unsuitable extinguishing media:	Avoid solid water stream as it may scatter and spread fire.
5.2.	Special hazards arising from the substance or mixture	
	Hazardous by products of fire:	Use water spray to cool fire exposed container surfaces and to protect personnel. Thermal decomposition can produce carbon monoxide (highly toxic) and carbon dioxide (an asphyxiant at sufficient concentrations).
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	
	Heating may cause container cracking due to increase in pressure. 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 suitable personal protective equipment (see Section 8).

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	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	After removing the product, use water to wash the work space and used materials.
6.3.3.	Other information:	No information available.
6.4.	Reference to other sections	
	-	

## SECTION 7. Handling and storage

7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Refer to the manufacturer's recommendations.
	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.

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	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

## SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
-	-	-	-	-

Substance: -

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

8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	Use 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 tested and approved under appropriate standards such as EN 166(EU).
8.2.2.2.	Skin protection:	
	Hand protection:	Handle with chemical resistant gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
	Other skin protection:	No specific protective equipment required.
8.2.2.3.	Respiratory protection:	Use when overexposure potential. Improper use of respirators is dangerous.
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/odour threshold:	No information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
Flash point:	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
pH:	No information available	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available

### 9.2. Other information

-

## SECTION 10. Stability and reactivity

10.1.	Reactivity:	Not reactive under normal 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:	No information available.

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10.4.	Conditions to avoid:	Contact with incompatible materials and temperature extremes.
10.5.	Incompatible materials:	Strong oxidizers.
10.6.	Hazardous decomposition products:	Does not decompose under normal conditions. During fire, thermal decomposition can produce carbon monoxide (highly toxic) and carbon dioxide (as asphyxiant as sufficient concentrations).

### SECTION 11. Toxicological information

#### 11.1. Information on toxicological effects

##### Acute toxicity:

Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	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	-	-
Dermal:	No information available	-	-
Inhalation:	No information available	-	-

##### Aspiration hazard:

-

##### Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	No information available	rabbit	-	-	mild skin irritation
Serious irritation to eyes:	No information available	rabbit	24 h	-	eye irritation



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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 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:		No information available			

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

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

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

### 12.3. Bioaccumulative potential

Octanol-water partition coefficient (log K<sub>ow</sub>)

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 <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (Daphnia)	EC <sub>50</sub>	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
No information available	No information available	No information available	No information available	-

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	Adsorption / desorption				
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-
12.5.	Results of PBT and vPvB assessment				
	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.				
12.6.	Endocrine disrupting properties				
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.				
12.7.	Other adverse effects				
	No information available				
SECTION 13. Disposal considerations					
13.1.	Waste treatment methods				
13.1.1.	Product/Packaging disposal:				
	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:				
	Disposal must be made according to official regulations.				
13.1.3.	Waste treatment – relevant information:				

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	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:
	-

#### SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by inland waterways (ADN)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)
UN number:	Not subject to transport regulations



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UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Further information:	
-	

## SECTION 15. Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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

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	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment	
	-	

SECTION 16. Other information			
16.1.	Indication of changes:		-
16.2.	Abbreviations and acronyms:		ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:		Manufacturer's MSDS file.
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
	Classification		Classification procedure
	-		-
16.5.	Relevant H statements (number and full text)		
	H:	H90 H02 314 315 319	May be corrosive to metals. Harmful if swallowed. Causes severe skin burns and eye damage. Causes skin irritation. Causes serious eye irritation.
16.6.	Training advice:		-

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16.7.	Further information:	<p>"X" in the product code marks different volumes (different packaging of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>
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<b>ANNEX: Exposure scenario resulting to Chemical safety assessment</b>
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