

### CONGO RED PUCHTLER KIT

The kit contains:

Congo Red, Puchtler reagent Hematoxylin G1 Histanol 100 Sodium hydroxide, solution



## According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

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Trading name:	CONGO RED PUCHTLER REAGENT				
Product code:	CRPR-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

SECTION	ON 1: Identification of	the substance	e/mixture	and of the company/undertaking	
1.1	Product identifier				
	Trading name:	CONGO RE	CONGO RED PUCHTLER REAGENT		
	Chemical name:	-			
	Catalogue number:	CRPR-OT-X			
1.2	Relevant identified us	es of the subs	tance or n	nixture and uses advised against	
	Uses:		For use	with Congo Red Puchtler kit.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses advi	sed against:	duct is intended for use only as an <i>in vitro</i> diagnostic device, registered at the Agency for Medicinal Products and Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplier	of the safety	data shee	t	
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2	2404039	
	e-mail of competent p	person:	msds@b	<u>piognost.hr</u>	
	National contact:		-		
1.4	Emergency telephone	number			
	National Protection a	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ON 2. Hazards identification					
2.1	Classification of the substar	Classification of the substance or mixture				
2.1.1	Classification according to F	Regulation (EC) No 1	272/2008 (CLP)			
	Hazard class and ca	tegory code:	Hazard statements*:			
	Carc. 1B H350					
2.1.2.	Additional information	Additional information				
	-					
*For fu	ll text of Hazard- and EU Haza	ard-statements: see S	SECTION 16			
2.2	Label elements					
	Product identification:	Product identification: CONGO RED PUCHTLER REAGENT				
	Identification number:	Identification number: -				
	Authorization number:	-				



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	Hazard pictograms:	GHS08			
	Signal word:	Danger			
	Hazard statements:	H350 May cause cancer.			
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P308+P313 If exposed or concerned: Get medical advice/attention.			
	Supplemetal hazard information (EU):	-			
2.3	Other hazards				
	Endocrine Disrupting Prope	rties:			
	No known endocrine disrupting properties				
	<b>Results of PBT and vPvB ass</b> PBT or a vPvB.	<b>sessment</b> : According to the results of its assessment, this substance is not a			
	(Direct Red 28 C.I.) Included into Regulation (EC) No. 1907/2	n the Candidate List of Substances of Very High Concern (SVHC) according 2006 (REACH).			

SECTION 3. Cor	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)		
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		

SECTIO	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.			



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	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 medi	cal attention and special treatment needed		
	-			

SECTIO	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:	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 environm	ent with extinguishing media.			

SECTIO	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. 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 ( (see Section 8).	case of inadequate ventilation use adequate airways protective equipment		
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 and involved materials with water.		
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).		
6.4	Reference to other sections			
	-			

SECTIO	ON 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.		
	Measures to prevent aerosol and dust generation	1:	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. The	roughly was	h hands after work and before eating.		
7.2	Conditions for safe storage, including any incomp	oatibilities			
	Technical measures and storage conditions:		htly closed and upright set containers in a ated storage roomsat temperatures ranging 25 °C.		
	Packaging materials:	Manufactu containers.	rer's original packaging. Avoid metal		



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	Requirements for storage rooms and vessels:		Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:  Further information on storage conditions:		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.
			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. Expo	sure contr	ols/personal	protec	tion					
-	parameters	<u> </u>	<u>.                                      </u>						
Substance		CAS N	CAS No		Occupational exposure limit values/short term values		Bi	Biological limit values	
				ppm		mg/m³		3	
-		-		-		-		-	
Substance name:	-								
EC No:	-	CAS No:	-						
DNEL									
				Industrial					
Route of	А	cute		Acute		Chronic		Chronic	
exposure:	effe	ct local	effec	t systemic		effect local		effect systemic	
Oral	-		-		-			-	
Inhalation	-		-		-			-	
Dermal	-		-		-			-	
Critical physical pa	arameters:	solubility, flar	nmabili	ty, corrosivity:		-			
				Consumer					
Route of	Д	cute		Acute		Chronic		Chronic	
exposure:	effe	ct local	effec	ct systemic		effect local		effect systemic	
Oral	-		-		-			-	
Inhalation	-	-	-		-			-	
Dermal	-		-		-			-	
PNEC									



Environmental protection target

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	<u></u>				
Fresh wat	er		No information available		
Freshwate	er sediments		No information available		
Marine wa	ater		No information available		
Marine se	ediments		No information available		
Food chai	in		No information available		
Microorganisms in sewage treatment Soil (agricultural) Air			No information available		
			No information available		
			No information available		
0.0					
8.2	Exposure controls				
8.2.1.	Appropriate engineering cont	rols			
	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 equipmen	nt			
8.2.2.1.	Eye and face protection:	levels	glasses that stick to face (EN 166) or visor in case of lower of concentration in air; protective gas mask that covers the face in case of higher levels of concentration in air.		
8.2.2.2.	Skin protection				
	Hand protection:	Protec	ctive nitrile gloves, 0.11 mm thick (EN 374).		
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) ong sleeves (EN 340) and shoes that cover the entire foot.		
8.2.2.3.	Respiratory protection:	Suitable mask (EN 136) or half mask (EN 140) equipped with combined "A1 + Form" filter (EN 143) used when concentratilevels exceed GVI.			
8.2.2.4.	Thermal hazards:	No info	ormation available		
8.2.3.	Environmental exposure contr	ols			
	Substance/mixture related measures to prevent exposure	See Se	ection 6		



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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

9.1	Information on basic physical and	chemical properties	
		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:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	рН:	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
.2	Other information		

SECTION 10. Stability and reactivity					
10.1 Reactivity	The product is stable under normal working and storage conditions.				



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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

11.1 Information	n on toxicological effects							
Acute toxic	ity:							
Route of exposure:	Method S	pecies	Do	se LD <sub>50</sub> /LC ATE <sub>mix</sub>	<sub>50</sub> or	Exposure tir	me	Results
Oral:	No information available rat			informatior lable	า -			15.200 mg/kg
Dermal:	No information - available			informatior lable	า -			-
Inhalation:	No information - available			informatior lable	า -			-
:								
Specific tar	get organ toxicity – sing	le expos	sure (S	TOT SE):				
	Specific effec	ts	Target organ			n		Note
Oral:	No information availab	nformation available			nation avail	able	-	
Dermal:	No information availab	e		No inform	No information available -			
Inhalation:	No information availab	е		No inform	nation avail	able	-	
Aspiration	hazard:	No	inforn	mation ava	ilable.			
Irritation ar	nd corrosion							
iiiidioii di	Exposure time		Speci	ies E	valuation	Metho	 od	Note
Skin corrosion/irritation:	No information	int	•	on in	o formation vailable	No inform available		-
Serious eye damage/irritation	No information	on inf	No No information inform available available		formation	No inform available	nation	-
Sensitizatio	on							
Skin sensitization:	No informatio	n availa	ble					



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Respiratory sensi	Respiratory sensitization: No i			able						
:										
Sympto	ms related	to the pl	nysical, chemic	al and toxicolog	ical characteristi	cs				
Oral exposure:	and	loss of c	to occurrence of strong sensation of stinging, headache, vertigo, intoxication consciousness after exposure to higher levels of concentration. If denaturants dyspepsia may occur (such as vomiting).							
Dermal exposure	: Def	atting, dr	ry skin.							
Inhalation exposi	ure: Bro	nchocons	eye irritation and upper respiratory system (stinging sensation, irritation). nstriction is possible. Possible symptoms include CNS symptoms such as vertigo, intoxication and loss of consciousness after exposure to higher levels of ion.							
Eye exposure:	Spla lesio	-	cause discom	fort, stinging sei	nsation, conjunct	ival redness, co	rneal surface			
Repeate	ed dose tox	cicity (sub	acute, subchro	onic, chronic)						
,	Do	se	Exposure time	Species	Method	Evaluation	Note			
Subacute oral	No info available	rmation	No information available	No information available	No information available	No information available	-			
Subacute dermal	No info available	rmation	No information available	No information available	No information available	No information available	-			
Subacute inhalation	No info available	rmation	No information available	No information available	No information available	No information available	-			
Subchronic oral	No info available	rmation	No information available	No information available	No information available	No information available	-			
Subchronic dermal	No info available		No information available	No information available	No information available	No information available	-			
Subchronic inhalation	No info available		No information available	No information available	No information available	No information available	-			
Chronic oral	No info available		No information available	No information available	No information available	No information available	-			
Chronic dermal	No info available	rmation	No information available	No information available	No information available	No information available	-			



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Chronic inhalation	No i availa	nformation ble	No information available	No information available	No information available	No informatic available	on	-
Sp	ecific target	organ toxicit	y – repeated e	xposure (STOT	RE):			
· · · · · ·			Specific effec	ts	Target o	rgan		Note
Subacute o	ral	No informa	tion available		No information	n available	-	
Subacute de	ermal	No informa	tion available		No information	n available	-	
Subacute in	halation	No informa	tion available		No information available -			
Subchronic	oral	No informa	tion available		No information	n available	-	
Subchronic	dermal	No informa	tion available		No information	n available	-	
Subchronic	inhalation	No informa	tion available		No information	n available	-	
Chronic ora	l	No informa	tion available		No information	n available	-	
Chronic der	mal	No informa	tion available		No information	n available	-	
Chronic inh	alation	No informa	tion available		No information	n available	-	
Mu Ge Mu Ge Re	CMR effects (carcinogenicity; mutagenicity; re Carcinogenicity:  Mutagenicity in vitro: Genotoxicity: Mutagenicity in vivo: Germ cell mutagenicity: Reproductive toxicity:  Summary of evaluation of the CMR properties:				to have carcinog ation available ation available ation available ation available of damaging the ation available			r humans.
		other hazard						
		upting prope e/mixture do	rties: pes not conta	ain				
coi dis Art reg Re	mponents co rupting pro ticle 57(f) gulation (EU	onsidered to perties acco or Commis ) 2017/2100	have endocri rding to REAG sion Delegat or Commissi at levels of 0.1	ne CH ed on				
		ion:						



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SECTION 12. E	cologic	al inforn	nation				
12.1 Toxicit	у						
Acute (short-te toxicity	rm)	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 μ	olants	IC <sub>50</sub>	4 days	No information available	No information available	No information available	-
Other organism	าร	-	-	_	-	_	-
Chronic (long-t toxicity	erm)	Dose	Exposure time	Species	Method	Evaluation	Note
		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 μ	olants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organism	ıs	-	-	-	-	-	-
		nd degrad	dability				
Abioti	degra						
	Deg	gradation	half-lives	Method	Evaluation		Note
Marine water	No in	formatio	n available	No information available	No informatio available	on -	
Fresh water	No in	formatio	n available	No information available	No information	on -	
Air	No in	formatio	n available	No information available	No information	on -	
Soil	No in	formatio	n available	No information available	No informatio	_	



Chronic toxicity on

crustacea (Daphnia)

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Biod	egradation										
% Degrada		Time (days	5)	N	Method		Evaluatio	n		Note	
No information available	on No		mation	No inf availat	ormation ole	No in availa	formation able		No information available		
	ccumulative		ficiont	Una Kou	Δ			1			
Octanol-water partition  Value Concentration			оН	°C Method			Evaluation		Note		
-	-	-			-		_		-		
Bioco	oncentration	factor (BCF	)								
Value		Species			Method	Evaluation		Note			
No information	on No availa		nation	No info	ormation ble		informati ilable	on	-		
Chro	nic ecotoxici	ty									
Val	ue	Dose		osure ime	Species	M	1ethod	Evalu	ation	Note	ļ
Chronic toxici	ty on fish	LC <sub>50</sub>	No infor	mation	No information	No info	rmation	No inform	ation	-	

crusta	cea ( <i>Dapnnia</i> )		available	available	available	available	
12.4	Mobility in so	il					
	Known or pre	dicted distributi	on in environm	nental compar	tments:		
	No information	n available					
	Surface tension	n:					
	Value	°C	Concentra	ation	Method		Note
	No information available	No information available	No informa available	ition No in	formation ble	-	

available

information

available

information

available

information

No

available

information

 $EC_{50}$ 



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Ad	sorption /	desorption					
Transport	A/D	coefficient y's constant	log Kow	Evaporation rate	e Method	Note	
Soil-water	No available	information e	No information available	No information available	No information available	-	
Water-air	No available	information e	No information available	No information available	No information available	-	
Soil-air	No available	information e	No information available	No information available	No information available	-	
12.6. End	docrine dis	srupting propert	ies		d to boy o ondo sino o	diamenting prop	outi os
The	e substanc	e/mixture does	not contain co	•	d to have endocrine o		
Reg	gulation (E	(U) 2018/605 at I	evels of 0.1%	or higher.			
12.7. Otl	her advers	e effects					
No	information	on available					
SECTION 1	3 Disnosa	l consideration	c				
		tment methods	<u> </u>				
S		ckaging disposa disposal to the l		uthorized by the Min	istry of Environmental	I and Nature	
13.1.2. V	Vaste code	es/waste designa	ations accordir	ng to Law:			
P	ackaging t	that contains res	idual hazardo	us substances or is co	ontaminated with haz	ardous substan	ces



Waste treatment – relevant information:

13.1.3.

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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 recommendat	ions:						
	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 provision	ons:						
	-							
SECTION	I 14 TRANSPORT INFORMAT	ION						
	Transporting/shipment by roac	I (ADR)						
UN numb	oer:	Not subject to transport regulations						
UN prop	er shipping name:	-						
Transpor	t hazard class(es):	-						
Packing o	group:	-						
Environm	nentally hazardous:	-						
Special p	recautions for user:	-						
	Transporting/shipment by rail (	(RID)						
UN numb	oer:	Not subject to transport regulations						
UN prop	er shipping name:	-						
Transpor	t hazard class(es):	-						
Packing o	group:	-						
Environm	nentally hazardous:	-						
Special p	recautions for user:	-						
	Inland waterway transport (ADI	N)						
UN numb	oer:	Not subject to transport regulations						
UN prop	er shipping name:	-						
Transpor	t hazard class(es):	-						
Packing o	group:	-						
Environm	nentally hazardous:	-						
Special p	recautions for user:	-						
	Transporting/shipment by sea (IMDG)							



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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 of MARPOL 73/78 and the I	-
Transporting/shipr	nent 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: -	

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



## According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

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	mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, a amending Regulation (EC) No 1907/2006;  REACH Restrictions on the manufacturing, placing on the market and use of certain sections.
	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of
	Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safe of workers from the risks related to chemical agents at work;
Other EU regulations:	organic solvents in certain paints and varnishes and vehicle refinishing products a amending Directive 1999/13/EC;
	2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 20 on the limitation of emissions of volatile organic compounds due to the use
	and Commission Regulation (EC) No 1488/94 as well as Council Directi 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC a 2000/21/EC;

SECTIO	ON 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:	-



## According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

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Trading name:		CONGO RED PUCHTL	CONGO RED PUCHTLER REAGENT		
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16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
Classifi	catior	า	Classification procedure		
-	-		-		
16.5.	Rel	evant H statements (num	ber and full text)		
	H:	350 361d	May cause cancer. Suspected of damaging the unborn child.		
16.6.	Tra	ining advice:	-		
16.7.	Further information:		** "X" in the product code marks different volumes (different package the product)  7. Further information: We are not responsible for consequences in case of failure to comply		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

ANNEX: Exposure scenario resulting to chemical safety assessment
-



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Trading name:	HEMATOXYLIN G1				
Product code:	HEMG1-OT-X**	Revision date:	14 Nov 2022	Version:	7

SECTI	ON 1 IDENTIFICATION	OF THE SUB	STANCE/MI	XTURE AND OF THE COMPANY/UNDERTAKING	
1.1.	Product identifier				
	Trading name:	HEMATOX	HEMATOXYLIN G1		
	Chemical name:	-	-		
	Catalogue number:	HEMG1-OT-X**			
1.2.	Relevant identified use	es of the subs	stance or mi	xture and uses advised against	
	Uses:		Hematoxy	lin according to Gill for nuclear staining.	
	Uses advised against:		Only the i	dentified 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:	В	BioGnost Ltd.		
	Address:	N	Medjugorska 59, Zagreb +385 1 2409997 +385 1 2404039		
	Telephone number:	+			
	Fax no.:	+			
	e-mail of competent p	oerson: <u>n</u>	msds@biognost.hr		
	National contact:	-			
1.4.	Emergency telephone	number			
	National Protection and Rescue Dire		ectorate:	112	
	Medical information:			+385 1 2348 342	

SECTIO	SECTION 2 HAZARDS INFORMATION					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification (REGULATION (	EC) No. 1272/2008	3 (CLP)			
	Hazard class and cate	gory code:	Hazard statements*:			
	Acute Tox. 4	e Tox. 4 H302				
2.1.2.	Additional information					
	-					
*For fu	ll text of Hazard- and EU Hazard	d-statements: see S	Section 16			
2.2.	Label elements					
	Product identification:	ation: HEMATOXYLIN G1				
	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/protection/face protection.  P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.			
	Supplemetal hazard information (EU):	-			
2.3.	Other hazards				
	Endocrine Disrupting Properties:				
	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 CO	SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS						
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	ldentification 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	SECTION 4 FIRST AID MEASURES				
4.1.	Description of first aid measures				
	General notes:	-			
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.			
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.			



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Trading name:	HEMATOXYLIN G1				
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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 a	aider:	Treat symptomatically.		
4.2.	Most important symptoms	and eff	fects, both acute and delayed		
	Following inhalation:		alation of large amounts of vapors in inadequately ventilated perimeter cause coughing, sneezing, headache and nausea.		
	Following skin contact:		nt irritation. After short exposure, resorption effects are not likely. Long- n exposure may cause drying, cracking and tingling sensation of skin.		
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation burning sensation. If the symptoms persist, immediately call a physicia			
	Following ingestion:	burr abdo couç	Swallowing may cause irritation of mucosa, tingling sensation in the mountaining 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 immediat	e medio	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.			

SECTIO	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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Trading name:	HEMATOXYLIN G1				
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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 (s	ee Section 8).	
6.2.	Environmental precautions:		
	Do not dispose of in sewage, Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National orate (NPRD) on 112.	
6.3.	Methods and material for cor	tainment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.	
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.	
6.3.3.	Other information:	-	
6.4.	Reference to other sections		
	See Section 7 for information	about secure handling.	
	See Section 8 for information about personal protective equipment.		
	See Section 13 for information about containment.		

SECTIO	TION 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					



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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							
meters							
	CAS No		Occupational exposure limit values/short term values		Biological limit values		
			ppm	mg/m³			
	107-2	1-1	20/40	52/104	No infor	mation available	
Substance name:							
	CAS No:	-					
			Industrial				
A	Acute		Acute	Chron	ic	Chronic	
effe	ect local	effect systemic		effect local		effect systemic	
-		-		-		-	
-		-		35 mg/ kg (ethylene glyd	col)		
Dermal						106 mg/kg (ethylene glycol)	
Critical physical parameters: solubility, flammability, corrosivity: -							
Consumer							
	effe	CAS No:  CAS No:  Acute effect local  -	CAS No  107-21-1  CAS No: -  Acute effect local efferation -	CAS No  CAS No  CAS No  Doccupational values/short ppm  107-21-1  20/40  CAS No:  Industrial  Acute Acute effect local effect systemic  meters: solubility, flammability, corrosivity:	CAS No  CAS No  CAS No  CAS No  CAS No:  CAS No:	CAS No  CAS No  CAS No  CAS No  CAS No  CAS No  CAS No:  CAS No:	



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Product C	.oue.	HEINIGT-OT-X***		Revisio	m date.	14 INOV 2022	version. 7		
Route of		Acute		Acut		Chronic	Chronic		
exposure:		effect local	6	effect sys	temic	effect local	effect systemic		
Oral		-	-	-		-	-		
Inhalation		-	-			7 mg/kg (ethylene glycol)	-		
Dermal		-	-			-	53 mg/kg (ethylene glycol)		
PNEC									
Environme	ental prote	ction target			PNEC				
Fresh water					10 mg/l (	(ethylene glycol)			
Freshwater sediments					37 mg/kg	g (ethylene glycol)			
Marine water				_	1 mg/l (e	thylene glycol)			
Marine sediments					3.7 mg/k	g (ethylene glycol)			
Food chair	n				No information available				
Microorga	ınisms in se	ewage treatment			199.5 mg/l (ethylene glycol)				
Soil (agric	ultural)				1.53 mg/kg (ethylene glycol)				
Air				No information available					
8.2.	Exposur	e controls							
8.2.1.	Enginee	ring measures							
	measure	ce/mixture related es to prevent expo dentified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.					
	Structur exposur	al measures to pre e:	vent	No info	rmation av	vailable			
	_	ational measures t exposure:	O		zation of w work proce		other worker's influence		
	Technica exposur	al measures to pre e:	vent			rkspace ventilation in c els in air below permitt	•		
8.2.2.	Persona	l protection equip	ment						
8.2.2.1.	Eye and	face protection:	on: Safety glasses that stick to face (preventing splashing) (EN 166 visor.				ing splashing) (EN 166) oı		
8.2.2.2.	Skin pro	otection							
	Hand pr	Hand protection:		Glove n	naterial: ni	according to standard	I EN 374.		
				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:	filter f	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) acording to EN 14387) used when concentration levels exceed GVI.				
8.2.2.4.	Thermal hazards:	No information available					
8.2.3.	Environmental exposure controls						
	Substance/mixture related measures to prevent exposure:		See Section 6				
	Structural measures to prevent exposure:		Use modern equipment.				
	Organisational measures to prevent exposure:		Adapt the work process to the required working conditions of the workplace.				
	Technical measures to prevent exposure:		See Section 6				

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



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

SECTIO	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 TOXIC	COLOGICAL INFORM	ATION			
11.1. Informatio	n on hazard classes as	s defined in Reg	gulation (EC) No 1272	2/2008	
Acute toxic	city:				
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 ta	rget organ toxicity – s	ingle exposure	(STOT SE):		
Specific eff		fic effects	Target o	organ	Note
Oral exposure:	No information	No information available		n available	-
Dermal exposure:	No information	No information available		n available	-
Inhalation exposure	: No information	available	No information	n available	-

Respiratory in	Respiratory irritation:		No information available					
Irritation and	corrosion							
	Exposure time	Species	Evaluation	Method	Note			



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Product code:	Н	EMG1-OT-X*	* R	evision da	ite:	14 Nov	/ 2022	Version:	7
			-		1				•
Skin irritation:		-	rab	oit	-		_	Slight irritation glycol)	n (ethylene
Eye irritation:		24 h	rab	bit	-		-	Slight irritation glycol)	n (ethylene
Sensitiza	ation								
Dermal exposure	: N	No information available							
Inhalation exposure:	N	No information available							
Sympto	ms rel	ated to the ph	nysical, chemi	cal and tox	icolog	ical charad	cteristics		
Oral exposure:		No informati	on available						
Dermal exposure	:	No informati	on available						
Inhalation exposi	ure:	No informati	on available						
Eye exposure:		Causes seriou	us eye damag	je					
Repeate	ed dos	e toxicity (sub	acute, subchr	onic, chror	nic)				
		Dose	Exposure time	Species		Method	E	Evaluation	Note
Subacute oral	No avail	information able	No information available	No informa available		No informa available	tion	No information Ivailable	-
Subacute dermal	No avail	information able	No information available	No informa		No informa	tion	No information available	-
Subacute inhalation		information able	No information available	No informa		No informa	tion	No information available	-
Subchronic oral		information able	No information available	No informa		No informa	tion	No information available	_
Subchronic dermal		information able	No information available	No informa		No informa	tion	No information available	-
Subchronic inhalation		information able	No information available	No informa available		No informa	availahle		-
Chronic oral		information able	No information available	No informa available		No informa available	tion	No information available	-



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Trading name:				HEN	ИАТС	OXYLIN G1			
Product code:	HE	MG1-OT-X	·* R	evision dat	e:	14 Nov 2022	,	Version:	7
Chronic dermal		No information information available		No information available		No information available	No info	ormation le	-
Chronic inhalation	No availa	information able	No information available	nformation information		No information available	No information available		_
Specific	target	organ toxicit	y – repeated (	avnosura (S	TOT R	)E).			
Specific	target	-	pecific effects		1011	Target orga	n		Note
Subacute oral			ition available		No i	nformation avail		-	
Subacute dermal			ition available			nformation avail		-	
Subacute inhalat	ion	No informa	ition available	2		nformation avail		-	
Subchronic oral		No informa	ition available	9	No i	nformation avail	able	-	
Subchronic derm	al	No informa	ition available	2	No i	information available		-	
Subchronic inhal	ation	No informa	ition available	available No information available		able	-		
Chronic oral		No informa	ition available	n available No inf		information available		-	
Chronic dermal		No informa	ition available	on available No		No information available		-	
Chronic inhalatio	n	No informa	ition available	on available No		lo information available			
CMR eff	ects (ca	arcinogenicit	y, mutagenici	ty, reproduc	tive t	oxicity)			
Carcino	genicity	<b>/</b> :	Current	Current studies on test animals did not indicate carcinogenic effects.					
Mutage	nicity <i>ii</i>	n-vitro:	Current	Current in vitro tests did not indicate mutagenic effects.					
Genoto				No information available					
Mutage						d not indicate m	utagenio	effects.	
Germ ce	ell muta	agenicity:		No information available					
Reprodu	uctive t	oxicity:	No toxi organs.	city on rep	orodu	ctive organs wa	as deter	mined in	reproductive
Summa	ry of ev	aluation of t	he CMR prope	erties: -					
11.2. Informa	tion on	other hazar	ds:						
11.2.1. Endocrii	ne disru	upting prope	rties:						
	nown ies that	endocrine affect huma	disrupting n health.						
11.2.2. Other in	ıformat	ion:							
-									



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Trading name:	HEMATOXYLIN G1				
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SECTION 12 E	COLOG	ICAL INFOR	RMATION	1:						
12.1. Toxici	ty		-						<u>,</u>	
Acute (short-te toxicity	erm)	Dose	Exposu time		Species	N	lethod	Evalu	ation	Note
Fish		LC <sub>50</sub>	96 hours		Fish		No ormation vailable	72.860 (ethylen	) mg/l e glycol)	-
Crustacea:	rustacea: EC <sub>50</sub> 48 hou		48 hour	·s	water flea		No ormation vailable	>100 (ethylen	mg/l e glycol)	_
Algae/aquatic	plants	IC <sub>50</sub>	8 days		algae		No ormation vailable	6.500-13. (ethylen	-	_
Microorganism	าร	LC <sub>50</sub>	72 hour	`S	-	_		-	-	-
Chronic toxicit	у	Dose	Exposu time		Species	M	lethod	Evalu	ation	Note
Fish	Fish LC <sub>50</sub> 96 hours		'S	No information available	No information available		No inform	nation	-	
Crustacea:		EC <sub>50</sub>	48 hour	`S	No information available	No information available		No inform	nation	_
Algae/aquatic	plants	IC <sub>50</sub>	72 hours		No information available	No information available		No inforn	nation	_
Other organism	ns	-	-		-	-		-		_
	ic degra									
		radation hal			Method			Evaluatio		Note
Marine water		ormation av			information availa			rmation ava		-
Fresh water		ormation av		-	information avail			mation ava		-
Air		ormation av			information availa			mation ava		-
Soil	No inf	ormation av	ailable	No	information availa	able	No info	rmation ava	ailable	-
Biode	gradati	on								
% Degradatio		Time (day:	5)		Method		Evaluat	tion	N	ote
No information	n No		mation I		nformation able		o informa vailable	tion I	No informa available	



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Produc	ct code:	Н	EMG1-OT	-X**		Revi	sion d	ate:	14 Nov 20	022	Version:	7
12.3.	Bioacc	umulati	ive potenti	al								
	Partitio	on coef	ficient: n-o	ctanol/\	wate	r (log Ko	ow):					
Value Concentration		рН		°C	М	ethod	Eva	luation		Note		
-	No information available		-		_	No info	ormation le	n No info availab	rmation le	-		
		ncentrat	ion factor (									
	'alue		Speci				Method		Evalu		Note	
No info availabl	rmation le		o in railable	format	ion	No info		on	No information available		No information available	
	Chroni	c ecoto	oxicity	se		osure	Sp	ecies	Method	Eva	lluation	Note
Chronic	toxicity			i.	No information available		No information available		No informatio available	No inf	ormation	-
	toxicity ea ( <i>Dapl</i>		EC <sub>50</sub>	i i	No	mation	No infor	No ormation informa ilable available		n No inf availab	ormation ble	-
12.4.	Mobili	ty in so	il									
			dicted dist	ibution	in e	environm	nental o	compart	ments:			
	No info	ormatic	n available									
	Surface	e tensic	n:									
	Val	lue	°C		C	oncentra	ition		Method		No	ote
	No No information				ormation -							



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Trading name:		HEMATO	DXYLIN G1		
Product code:	HEMG1-OT-X**	Revision date:	14 Nov 2022	Version:	7

	Adsorption / desorption				
Transpo	rt A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-wat	er No information available	No information available	No information available	No information available	-
Water-a	ir 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 asse	samont			
12.5.	Based on available data, the		contain any DRT or y	PvR substances	
	based on available data, the	product does not (	Londain any PDT OF V	T VD SUDSTAIRES.	
12.6.	Endocrine disrupting proper	ies			
	No known endocrine disrupt		affect the environm	nent.	
		J1 1			
12.7.	Other adverse effects				
12.7.	Other adverse effects  No adverse effects are expec	ted.			
12.7.		ted.			
	No adverse effects are expec				
SECTIO	No adverse effects are expec				
SECTIO	No adverse effects are expec	TIONS			
<b>SECTIOI</b> 13.1.	No adverse effects are expect  N 13 DISPOSAL CONSIDERA  Waste treatment methods	TIONS	rized by the Ministr	y of Environmental	and Nature
<b>SECTIOI</b> 13.1.	No adverse effects are expect  N 13 DISPOSAL CONSIDERA  Waste treatment methods  Product/Packaging disposal  Submit for disposal to the	TIONS  al: legal person autho	·	y of Environmental	and Nature
<b>SECTIOI</b> 13.1.	No adverse effects are expected N 13 DISPOSAL CONSIDERAL Waste treatment methods  Product/Packaging disposal Submit for disposal to the Protection.	TIONS  al: legal person autho	·	y of Environmental	and Nature
<b>SECTIOI</b> 13.1.	No adverse effects are expect  N 13 DISPOSAL CONSIDERA  Waste treatment methods  Product/Packaging disposal Submit for disposal to the Protection.  Waste codes/waste design No information available	TIONS  al: legal person author ations according to	·	y of Environmental	and Nature
<b>SECTIOI</b> 13.1.	No adverse effects are expect  N 13 DISPOSAL CONSIDERA  Waste treatment methods  Product/Packaging disposal Submit for disposal to the Protection.  Waste codes/waste design	TIONS  al: legal person author ations according to	·	y of Environmental	and Nature
<b>SECTIOI</b> 13.1. 13.1.1.	No adverse effects are expect  N 13 DISPOSAL CONSIDERA  Waste treatment methods  Product/Packaging disposal Submit for disposal to the Protection.  Waste codes/waste design No information available	TIONS  al: legal person author ations according to	·	y of Environmental	and Nature
<b>SECTIOI</b> 13.1. 13.1.1.	No adverse effects are expect  N 13 DISPOSAL CONSIDERA  Waste treatment methods  Product/Packaging disposal Submit for disposal to the Protection.  Waste codes/waste design No information available  Waste treatment – relevant	al: legal person authorations according to	·	y of Environmental	and Nature



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Trading name:	HEMATOXYLIN G1					
Product code:	HEMG1-OT-X**	Revision date:	14 Nov 2022	Version:	7	

13.1.5.	Other disposal recomme	ndations:
	authorized by the ministr	oduct's remains into the sewage system. Submit the remains to the collectors ry in charge. Do not dispose of the packaging into the sewage system. Submit lectors authorized by the ministry in charge. Do not dispose of in places where
13.1.6.	Relevant Community pro	ovisions:
	-	
SECTION	N 14 TRANSPORT INFORM	MATION
	Transporting/shipment by	road (ADR)
UN numl	ber:	Not subject to transport regulations.
UN prop	er shipping name:	-
Transpor	t hazard class(es):	-
Packing (	group:	-
Environm	nentally hazardous:	-
Special p	recautions for user:	-
	Transporting/shipment by	rail (RID)
UN numl	ber:	Not subject to transport regulations.
UN prop	er shipping name:	-
Transpor	t hazard class(es):	-
Packing (	group:	-
Environm	nentally hazardous:	-
Special p	precautions for user:	-
	Inland waterway transport	(ADN)
UN numl	ber:	Not subject to transport regulations.
UN prop	er shipping name:	-
Transpor	t hazard class(es):	-
Packing (	group:	-
Environm	nentally hazardous:	-
Special p	precautions for user:	-
	Transporting/shipment by	sea (IMDG)
UN numl	ber:	Not subject to transport regulations.
UN prop	er shipping name:	-
Transpor	t hazard class(es):	-
Packing (	group:	-
Environm	nentally hazardous:	-



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Trading name:	HEMATOXYLIN G1					
Product code:	HEMG1-OT-X**	Revision date:	14 Nov 2022	Version:	7	

Special precautions for user:	-		
Transporting/shipment by a	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>SECTI</b> 15.1.	ON 15 REGULATORY INFORMATION  Safety, health and environmental regulations/legislation specific for the substance or mixture		
	EU regulations		
	Authorization and/or restrictions of use		
	Authorizations:	-	
	Restrictions:	-	
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);	
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-	
	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	



#### **SAFETY DATA SHEET** BIOGNOST® According to Regulation (EC) No. 1907/2006

amended by Regulation (EU) No. 2020/878

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Trading name:		НЕМАТО	XYLIN G1	_	
Product code:	HEMG1-OT-X**	Revision date:	14 Nov 2022	Version:	7

15.2.	Chemical safety assessment
	None

SECTIO	CTION 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)			
Classifi	cation	Classification procedure		
-		-		
16.5.	Relevant H statements (numb	er 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** 



## According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

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

1.1		ON 1: Identification of the substance/mixture and of the company/undertaking  Product identifier			
1,1		HICTANOL	100		
	Trading name:	HISTANOL 100			
	Chemical name:	Ethyl alcohol			
	Catalogue number:	H100-X**			
1.2	Relevant identified us	es of the subs	tance or n	nixture and uses advised against	
	Uses:		For use	in histocytology and cytology sample processing.	
	Uses advised against:		Only the identified uses are advised. Unsuitable for human comsumption.		
	Reason why uses advised against:		The product is intended for use only as an <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:	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 a	National Protection and Rescue Direc		112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards identification			
2.1	Classification of the substance or mixture			
2.1.1	Classification according to Reg	ulation (EC) No 12	272/2008 (CLP)	
	Hazard class and catego	ory code:	Hazard statements*:	
	Flam. Liq. 2		H225	
2.1.2.	Additional information			
	-			
*For ful	ll text of Hazard- and EU Hazard-	statements: see Sl	SECTION 16	
2.2	Label elements			
	Product identification:	HISTANOL 100		
	Identification number:	-		
	Authorization number:	-		



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

	Hazard pictograms:	GHS02	
	Signal word:	Danger	
	Hazard statements:	H225 Highly flammable liquid and vapor.	
	Precautionary statements:	P210 Keep away from heat, hot sparks, open flames and other ignition sources. No smoking.  P233 Keep container tightly closed.  P280 Wear protective gloves/protective clothing/eye/protection/face protection.  P403+P235 Store in a well-ventilated place. Keep cool.	
	Supplemetal hazard information (EU):	-	
2.3	Other hazards		
	The product has no other known specific hazards for human or environment.		
	Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.		
	Endocrine disrupting property:	Based on available data, does not contain endocrine disruptors.	

SECTION 3. Composition/information on ingredients					
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)	
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- 0147	min. 99 %	ethanol	Flam. Liq. 2; H225	

SECTI	SECTION 4. First aid measures			
4.1	Description of first aid measures			
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.		
	Following inhalation:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.		
	Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.		



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

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

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



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

	ON 6. Accidental release meas				
6.1	Personal precautions, protecti	ve equipment and emergency procedures			
6.1.1.	For non-emergency personne				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.			
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:				
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.				
6.2	Environmental precautions:				
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.				
	Methods and material for containment and cleaning up				
6.3	Methods and material for con	tainment and cleaning up			
6.3.1.	Methods and material for con Bunding, covering of drains; capping procedures:	tainment and cleaning up  Sand protective barrier or barriers made of similar materials.			
	Bunding, covering of drains;				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.  Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal.  During the collection, placement, disposal of the waste, wear appropriate individual protective equipment.  Flush the remains with plenty of water. The product loses its flammability, if			
6.3.1.	Bunding, covering of drains; capping procedures:  Cleaning up:	Sand protective barrier or barriers made of similar materials.  Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal.  During the collection, placement, disposal of the waste, wear appropriate individual protective equipment.  Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).  Secure proper ventilation. Do not use incompatible materials (see Section			

SECTION 7. Handling and storage			
7.1	Precautions for safe handling		
7.1.1.	Protection measures		



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

	Measures to prevent fire:		Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use non-sparkling tools and equipment.		
	Measures to prevent aerosol and dust generatio	n:	Ensure adequate ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:		Protect against electrostatic charges.		
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. The	oroughly was	sh hands after work and before eating.		
7.2	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:	Store in a well-ventilated place, protected from sunlight, away from sources of heat and ignition, in its original, unopened and hermetically sealed packaging, away from oxidizing agents, food, feed and articles of consumption.			
	Packaging materials:	Manufacturer's original packaging.			
	Requirements for storage rooms and vessels:	Keep away tightly clos	r from food and drink. Keep the containers sed.		
	Advices for storage equipment:	be resistar	ge must be made of hard material; floors must nt to chemicals. There must be no drain that eads into sewage system. Secure proper n.		
	Further information on storage conditions:	and do n	ace the unused material in the storage room of use empty containers for storing other Do not store with incompatible materials (see )).		
7.3	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	-			

SECTION 8. Exposure controls/personal protection					
8.1 Control parameters	Control parameters				
Substance	CAS No		exposure limit term values	Biological limit values	
		ppm	mg/m³	_	
Ethanol	64-17-5	1000/-	1900/-	-	
		•			
Substance name: -					



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									rage o or r	<i>'</i>
Trading na	ame:					HIST	ANOL 100			
Product co	ode:	H100-X	<b>*</b> *		Revisio	on date:	05 Dec	2022	Version:	6
		1	I				1			
EC No:		-	CAS No	:	-					
DNEL										
				ı	Inc	dustrial				
Route of		Acu			Acute		Chronic		Chronic	
exposure:		effect	local	effe	ct systemic		effect local		effect systemic	
Oral		1000	13	-			-			
Inhalation		1900 mg (ethanol)		-		-		380	0 mg/m³ (ethanol)	
Dermal		-		-				343	3 mg/kg (ethanol)	
Critical phy	sical para	ameters: s	olubility,	flamm	ability, cor	rosivity:	-			
					Co	nsumer	<u> </u>			
Route of Acute		cute		Acute		Chronic		Chronic		
exposure:		effec	t local	effe	ct systemi	С	effect local		effect systemic	
Oral		-		-		-		87	mg/kg bw/day (eth	anol)
Inhalation		950 m (ethan	_	-		-		114	4 mg/m³ (ethanol)	
Dermal		-		-		-		200	6 mg/kg (ethanol)	
PNEC										
Environmer	ntal prote	ection tar	get			PNEC				
Fresh water	ſ					0.96 mg/l (ethanol)				
Freshwater	sedimen	ts				3.6 mg/kg (ethanol)				
Marine wat	er					0.79 mg/l (ethanol)				
Marine sed	iments					2.9 mg/kg (ethanol)				
Food chain						380-720 mg/kg (ethanol)				
Microorgan	nisms in s	ewage tre	eatment			580 mg/l (ethanol)				
Soil (agricu	ltural)					0.63 mg/kg (ethanol)				
Air				no information available						
8.2	Exposu	re contro	s							
8.2.1.	Approp	riate eng	ineering	control	s					
Substance/mixture related measures to prevent exposure during identified uses:			concentra concentra existing	ation limit it ation levels c scientific and	is the em lown to a i technolog	ial with no contronployer's duty to lessential indicate to lessential indicate the lessential indicate in the lessential indicate	keep e by			
	Structu exposu		ral measures to prevent			In accordance with Section 7.				



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

	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent ex	(posure:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation.		
	'	'	Use non-sparkling ventilation system.		
			Provide appropriate personal protective equipment, safety shower and eye-wash station.		
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:		propriate, chemical-proof protective glasses/face shield (EN 321-1:2022, EN 166).		
8.2.2.2.	Skin protection				
	Hand protection:	Use ap	se appropriate, chemical-resistant protective gloves (EN 374).		
	Other skin protection:	Use ap	propriate protective clothing.		
8.2.2.3.	Respiratory protection:	concer in the contac	e of normal usage and ventilation, it is not necessary. If necessary are a self-contained breathing apparatus. For short and if the oxygen content of the air is greater than 18 %, use ective gas mask with filter A (EN 14837/A1).		
8.2.2.4.	Thermal hazards:	No the	ermal hazards known.		
8.2.3.	Environmental exposure controls				
	Substance/mixture related measures to prevent exposure:	See Se	ction 6		
	Structural measures to prevent exposure:	Use mo	odern equipment.		
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.		
	Technical measures to prevent exposure:	See Se	ction 6		

SECTI	SECTION 9. Physical and chemical properties						
9.1	Information on basic physical and	Information on basic physical and chemical properties					
		Value	Method				
	Physical state:	liquid	No information available				
	Colour:	colourless	No information available				
	Odour/odour threshold:	ethanol like/no information available	No information available				
	Melting point / freezing point:	No information available	No information available				



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

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

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

SECTIO	SECTION 11. Toxicological information						
11.1	11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008						
	Acute toxic	ity:					
Route of exposure:		Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results	



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Trading name:			HISTANOL 100					
Product code:	H100-X**	F	Revision date: 05 Dec 2022		2022	Vers	ion: 6	
Oral:		rat (ethanol	)	LD <sub>50</sub>	1	_	-	7.060 mg/kg
Dermal:	-	rabbit (ethano	-	LD <sub>50</sub>		-		>20.000 mg/l
Inhalation:	-	rat (ethanol)		LC <sub>50</sub>		4 h		>8.000 mg/l
Specific t	arget organ toy	xicity – single ex	nocuro (S)	OT CEV				
Specific t		pecific effects	posure (3)	O ( 3E)	Target orga	n		Note
Oral:	•	ion available		No inf	ormation avail			note
Dermal:		ion available			ormation avail			
Inhalation:		ion available			ormation avail		_	
innalation:	NO Informat	ion available		NO INTO	ormation avail	able	-	
Aspiratio	n hazard:		No inform	nation a	vailable.			
Irritation	and corrosion					1		
	Expo	sure time	Speci	es	Evaluation	Method		Note
Skin corrosion/irritation	n: -		-		-	-	-	
Serious eye damage/irritation	-		-		-	-	-	
Sensitiza	tion							
Skin sensitization:		information ava	ailable.					
Respiratory sensit		information ava						
Sympton	ns related to the	physical, chem	ical and to	oxicoloc	gical character	istics		
Oral exposure:	unconscio	on of great ousness and alco may occur. Rep	ohol poiso	ning. In	case of swallo	wing great o	•	, nausea and
Dermal exposure:	After pro	longed or repe of skin.	eated exp	osure s	symptoms ma	ay include: o	defatting,	dryness and
Inhalation exposu	re.	e: Inhalation of great quantities may cause dizziness, euphoria and mild irritation of the mucous membranes.						
Eye exposure:	May caus	e irritation and ı	redness.					
Popostos	dosa tovisity (	subacute, subch	ronic chr	onic)				
repeated	Dose	Exposure time	Specie		Method	Evaluati	ion	Note



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Trading name:	HISTANOL 100				
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Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	_
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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



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Trading name:	HISTANOL 100				
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	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)					
	Carcinogenicity:	Based on available data, the classification criteria are not met.				
	Mutagenicity in vitro:	Based on available data, the classification criteria are not met.				
	Genotoxicity:	Based on available data, the classification criteria are not met.				
	Mutagenicity in vivo:	Based on available data, the classification criteria are not met.				
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.				
	Reproductive toxicity:	Based on available data, the classification criteria are not met.				
	Summary of evaluation of the CM properties:	R Based on available data, the classification criteria are not met.				
11.2	Information on other hazards:					
11.2.1.	Endocrine disrupting properties:					
	Based on available data, does not contain endocrine disruptors.	in				
11.2.2.	Other information:					
_	-					

SECTION 12. Ecologic	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	golden orf	No information available	8.140 mg/l /48 h (ethanol)	-		
Crustacea:	EC <sub>50</sub>	48 hours	daphnia magna	No information available	7.800 mg/l (ethanol)	_		
Algae/aquatic plants	IC <sub>50</sub>	4 days	algae	No information available	5.000 mg/l / 7d (ethanol)	-		
Other organisms	-	-	-	-	_	-		
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-		



Value

Species

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		ANOL 100			
	Day data a state.				
	Revision date:	05 Dec 20	22	Version:	6
48 hours	No information available	No information available	No inform	nation _	
72 hours	No information available	No information available	No inform available	ation -	
-	-	-	-	-	
·					
ity					
f-lives	Method	Evaluatio	n	Note	
ailable	No information available	No information	n -		
ailable	No information available	No information available	า -	-	
ailable	No information available	No information available	n	-	
ailable	No information available	No information available		-	
ys)	Method	Evaluatio	n	Note	
rmation	No information available	No information available		No information available	
efficient (lo	og Kow)				
рН	°C Method	Evalu	ation	Not	e
_	-	-		•	
	рН	1	pH °C Method Evalu	pH °C Method Evaluation	pH °C Method Evaluation Not

Method

Evaluation

Note



												'age 13 of 17	
Tradin	ng name:					l	HISTAN	NOL 100	)				
Produ	ct code:	H10	0-X**		Revis	ion da	ate:	05 D	ec 202	22		Version:	6
BCF: 0.0	66	No availa	inform able	nation	No info		on	No info		on	-		
	Chronic 6	ecotoxic	ity										
	Value		Dose		osure ime	Spe	ecies	Meth	od	Evalı	uation	Note	<b>:</b>
Chronic toxicity on fish		LC <sub>50</sub>	No information available		No inforr availa	nation able	No informa availab		No inform availal		-		
Chronic toxicity on crustacea ( <i>Daphnia</i> )		EC <sub>50</sub>	No information available		No inforr availa	mation able	No informa availab		No information available		-		
12.4	Mobility	in soil											
			ted distribut	ion in e	environme	ental c	ompart	ments:					
	No inforr		available										
	Surface t		°C	<u> </u>	oncentrat	tion		Metho	d			Note	
	Lintormation intormation		No	No information No in		No inf	nformation						
	Adsorption	on / des	orption										
Transp	ort		oefficient s constant	lo	og Kow	Εν	/aporati	on rate		Method		Note	

No information

No information

No information

available

available

available

No information

No information

No information

available

available

available

12.5	Res	ults	of PBT	and	vPvB	asse	essment
	_						

No

No

No

available

available

available

Soil-water

Water-air

Soil-air

information

information

information

Based on available data, the product does not contain any PBT or vPvB substances.

No information

No information

No information

available

available

available



#### **SAFETY DATA SHEET** According to Regulation (EC) No. 1907/2006

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

12.6.	Endocrine disrupting prope	rties				
	Based on available data, do	Based on available data, does not contain endocrine disruptors.				
12.7.	Other adverse effects					
	Do not let the product or its	residues reach sewer system, waterways and soil.				
SECTIO	N 13. Disposal consideration	ons				
13.1	Waste treatment methods					
13.1.1.	Product/Packaging dispos					
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.					
13.1.2.	Waste codes/waste design					
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances					
13.1.3.	Waste treatment – relevar	nt information:				
	No information available					
13.1.4.	Sewage disposal – relevar					
	Waste must not be dispos	sed of into the sewage system.				
13.1.5.	Other disposal recommen	dations:				
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Unused product residues may be burnt.					
13.1.6.	Relevant Community prov	Relevant Community provisions:				
Disposal must be made according to official regulations.		ccording to official regulations.				
SECTIO	N 14 TRANSPORT INFORM	ATION				
	Transporting/shipment by r	oad (ADR)				
UN number:		1170				
	per shipping name:	Ethanol solution				
Transpo	ort hazard class(es):	3				
Packing	group:					



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Trading name:	HISTANOL 100				
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Environmentally hazardous:	_
Special precautions for user:	-
Transporting/shipment by rail (R	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (II	MDG)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	ll .
Environmentally hazardous:	-
Special precautions for user:	-
Further information: -	



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Trading name:	HISTANOL 100				
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15.1	EU regulations	nmental regulations/legislation specific for the substance or mixture				
	Authorization and/or restrictions of use					
	Authorizations:					
	Restrictions:	-				
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).				
		REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);				
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)					
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act				
15.2	Chemical safety assessme	ent				
	None					

SECTION 16. Other information	
16.1 Indication of changes:	-



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According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

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Trading name:	HISTANOL 100				
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16.2	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  IMDG: International Maritime Code for Dangerous Goods  IATA: International Air Transport Association  GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances  CAS: Chemical Abstracts Service (division of the American Chemical Society)  DNEL: Derived No-Effect Level (UK REACH)  LC50: Lethal concentration, 50 percent  LD50: Lethal dose, 50 percent  PBT: Persistent, Bioaccumulative and Toxic  vPvB: very Persistent and very Bioaccumulative			
16.3.	Key literature references and source of data:	Manufacturer's MSDS file.			
16.4.	Classification and procedure (1272/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)			
Classifi	cation	Classification procedure			
_		-			
16.5.	Relevant H statements (numb	er and full text)			
	H: 225	Highly flammable liquid and vapor.			
16.6.	Training advice:	-			
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product)  We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to chemical safety assessment
-



According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

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Trading name:	SODIUM HYDROXIDE, SOLUTION			-
Product code:	NH-OT-X**	Date of compilation:	21 Dec 2022	Version: 3

		tne substance	e/mixture a	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	SODIUM HY	SODIUM HYDROXIDE, SOLUTION		
	Chemical name:	-	-		
	Catalogue number:	NH-OT-X**	NH-OT-X**		
1.2.	Relevant identified use	es of the subst	ance or mix	cture and uses advised against	
	Uses:		or use with (	Congo Red Puchtler kit.	
	Uses advised against:	Oı	nly the iden	itified 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	Emergency telephone number			
	National Protection ar	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards identification				
2.1.	Classification of the substance or mixture				
2.1.1.	Classification according to Regula	Classification according to Regulation (EC) No 1272/2008 (CLP)			
	Hazard class and category	y code:	Hazard statements*:		
	Not identified as hazardous subs	tance.	-		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazard-st	atements: see S	ection 16		
2.2.	Label elements				
	Product identification:	SODIUM HYD	PROXIDE, SOLUTION		
	Identification number:	-			
	Authorization no.:	-			
	Hazard pictograms:	-			



### SAFETY DATA SHEET According to Regulation (EC) No. 1907/2006

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Trading name:	SODIUM HYDROXIDE, SOLUTION				
Product code:	NH-OT-X**	Date of compilation:	21 Dec 2022	Version:	3

	Signal word:	-	
	Hazard statements:	-	
	Precautionary statements:	-	
	Further information:	-	
2.3.	Other hazards		
	Endocrine Disrupting Properties:		
	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. Co	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)	
1310-73-2/ 215-185-5/ 011-002-00-6	-	0.7 - 1%	sodium hydroxide	Skin Corr. 1A; H314	

SECTION	ECTION 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 aid	der: Treat symptomatically.			
4.2.	Most important symptoms ar	nd 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.			



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Trading name:	SODIUM HYDROXIDE, SOLUTION				
Product code:	NH-OT-X**	Date of compilation:	21 Dec 2022	Version: 3	

	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		
	-		

SECTION	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.				

SECTIO	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).		see Section 8).			
6.2.	Environmental precautions:				
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.				
6.3.	Methods and material for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.			



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Trading name:		SODIUM HYDROXID	E, SOLUTION		
Product code:	NH-OT-X**	Date of compilation:	21 Dec 2022	Version: 3	

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

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



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Trading name:	SODIUM HYDROXIDE, SOLUTION				
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SECTION 8. Ex			ols/persona	al protec	tion			
8.1. Contr	rol para	meters			ı			
Substance		CAS I			cupational exposure limit alues/short term values		Biological limit values	
					ppm	mg/m³		
-			-			-	-	No information available
					•			
Substance name:	_							
EC No:	_		CAS No:	-				
DNEL								
					Inc	dustrial		
Route of		A	Acute		Acut	e	Chronic	Chronic
exposure:		effe	ect local	effe	ct sys	temic	effect local	effect systemic
Oral		-		-			-	-
Inhalation		-		-			-	-
Dermal		-		-			-	-
Critical physica	al parar	meters: s	solubility, fla	ımmabilit	ty, cor	rosivity:	-	
					Со	nsumer		
Route of			Acute		Acut		Chronic	Chronic
exposure:		effe	ect local	effe	ct sys	temic	effect local	effect systemic
Oral		-		-			-	-
Inhalation		-		-			-	-
Dermal		-		-			-	-
PNEC								
Environmental	l protec	tion tar	get			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 infor	mation available	



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Trading name:		SODIUM HYDROXID	E, SOLUTION	-
Product code:	NH-OT-X**	Date of compilation:	21 Dec 2022	Version: 3

8.2.	Exposure controls	posure 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 preexposure:	revent	No information available		
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to pr exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.		
8.2.2.	Personal protection equi	pment			
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) visor.			
8.2.2.2.	.2.2.2. Skin protection				
	Hand protection:		active gloves must be according to the EU Directive 2016/425/EEC and and EN 374.  Glove material: nitrile rubber  Glove thickness: ≥0.50 mm  Break through time: >480 min		
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) with long s (EN 13034), and shoes that cover the entire foot (EN 10335).		
8.2.2.3.	Respiratory protection:	filter f	ctive full face mask (EN 136) or half mask (EN 140) equipped with a cor organic vapors, type "A" (boiling point >65°C) acording to EN ) used when concentration levels exceed GVI.		
8.2.2.4.	Thermal hazards:	No inf	ormation available		
8.2.3.	Environmental exposure	controls			
	Substance/mixture relate measures to prevent expe		See Section 6		
	Structural measures to prescribe exposure:	revent	Use modern equipment.		
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.		
	Technical measures to prexposure:	event	See Section 6		

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



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Trading name:		SODIUM HYDROXID	E, SOLUTION	-
Product code:	NH-OT-X**	Date of compilation:	21 Dec 2022	Version: 3

	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour/odour threshold:	no odor/no information avaialble	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
	рН:	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		

SECTIO	SECTION 10. Stability and reactivity		
10.1.	Reactivity:	See subsections 10.3 through 10.5.	
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.	
10.3.	Possibility of hazardous reactions:	No information available	
10.4.	Conditions to avoid:	No information available	
10.5.	Incompatible materials:	No information available	
10.6.	Hazardous decomposition products:	No information available	

SECTIO	SECTION 11. Toxicological information				
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				



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Route of exposure:	Method	Species	Effective dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposi time	RACILITO
Oral exposure:	No information available	_	LD <sub>50</sub>	-	
Dermal exposure:	No information available	-	LD <sub>50</sub>	-	
Inhalation exposure:	No information available	-	LC <sub>50</sub>	_	-
Specific targ	get organ toxicity – s	ingle exposure	e (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	-	
Irritation and	a corrosion				
Irritation and	Exposure time	Species	Evaluation	Meth od	Note
Irritation and Skin irritation:		Species -	Evaluation -		Note -
	Exposure time	•		od	
Skin irritation: Eye irritation:	Exposure time -	-	-	od -	_
Skin irritation: Eye irritation: Sensitization	Exposure time	-	-	od -	_
Skin irritation: Eye irritation: Sensitization Dermal exposure:	Exposure time  No information avail	- lable	-	od -	_
Skin irritation: Eye irritation: Sensitization Dermal exposure:	Exposure time	- lable	-	od -	_
Skin irritation:  Eye irritation:  Sensitization  Dermal exposure: Inhalation exposure:	Exposure time  No information avail	lable	-	od	_
Skin irritation: Eye irritation: Sensitization Dermal exposure: Inhalation exposure:	Exposure time  No information avail	lable lable	-	od	_
Skin irritation: Eye irritation:  Sensitization  Dermal exposure: Inhalation exposure:  Symptoms r	Exposure time  No information avail	lable lable al, chemical an	-	od	_
Skin irritation:  Eye irritation:  Sensitization  Dermal exposure:  Inhalation exposure:  Symptoms r  Oral exposure:	Exposure time  No information available related to the physical No information ava	lable lable al, chemical an	-	od	_

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



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			tion available	No information available		
	CMR effects (	carcinogenicity	r, mutagenicity, re	eproductive toxicity)		
	Carcinogenici	ty:	Based on ava	ailable data, the classification criteria	a are not met.	
	Mutagenicity	in-vitro:	Based on ava	ailable data, the classification criteria	a are not met.	
	Genotoxicity:		Based on ava	ailable data, the classification criteria	a are not met.	
	Mutagenicity	in-vivo:	Based on ava	ailable data, the classification criteria	a are not met.	
	Germ cell mu	tagenicity:	Based on ava	ailable data, the classification criteria	a are not met.	
	Reproductive	toxicity:	Based on available data, the classification criteria are not met.			
11.2	Information o	n other hazard	s:			
11.2	Information o	n other hazard	S:			
11.2.1.	Endocrine dis	rupting proper	ties:			
	components endocrine according to Commission 2017/2100 o	e/mixture does considered disrupting REACH Artic Delegated reg r Commission 05 at levels o	to have properties le 57(f) or ulation (EU) Regulation			
11.2.2.	Other informa	ation:	:			

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



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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)	Time (days) Method		Note	
No information available No information		No information No information available available		No information available	

#### 12.3. Bioaccumulative potential

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

L							
	Value	Concentration	рН	°C	Method	Evaluation	Note
	-	No information available	-	_	No information available	No information available	-

Bioconcentration factor (BCF)



#### **SAFETY DATA SHEET** BIOGNOST® According to Regulation (EC) No. 1907/2006

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V	/alue		Species		Me	ethod		Evaluation		Note		
No info	ormation le		informati ailable		n No informatio available				No information available	No information avai		ailable
	Chron	ic ecoto	xicity									
	Value	е	Dose		osure ime	Sp	ecies	Method	Eva	luation	Note	
Chronic	c toxicity	y on fish	LC <sub>50</sub>	No infori availa	mation able	No infor avail	mation able	No information available	No info	ormation lle	-	
	c toxicity ea ( <i>Dapi</i>		EC <sub>50</sub>	No infori availa	mation able	No infor avail	mation able	No information available	No info	ormation lle	-	
12.4.		ity in soi	l dicted distributi	on in e	environm	ental	compart	ments:				
	No inf	ormatio	n available									
	Surfac	e tensio	n:									
	Va	lue	°C	C	oncentra	tion		Method		N	lote	
	No inform availat		No information available		informat iilable	tion	No inf	ormation avail	able	_		
	Adsor	ption / c	lesorption									
Transpo		A/D o	coefficient 's constant	lc	g Kow		Evapo	ration rate		Method	Note	
Soil-wa	tor :	lo vailable	information	No ir availa	nformatic able		o inform ⁄ailable	nation	No info	ormation lle	-	
Water-air		lo vailable	information	No ir availa	nformatic able		o inform ⁄ailable	nation No info		ormation lle	-	
				No ir								



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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
12.7.	No information available
	No information available
	N 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:
13.1.2.	No information available
	NO IIIOITIation 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:



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SECTION 14. Transport information	
Transporting/shipment by	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by	rail (RID)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport	(ADN)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by	sea (IMDG)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by	air (ICAO-TI/IATA-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-



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Special precautions for us	ser:	-
Further information:	-	

15.1.	ON 15. Regulatory information Safety, health and environment	nmental regulations/legislation specific for the substance or mixture						
	EU regulations							
	Authorization and/or rest	trictions of use						
	Authorizations:	-						
	Restrictions:	-						
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);						
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-						
	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 assessme	ent						
	None							

SECTION 16. Other information	
16.1. Indication of changes:	-



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16.2.	Abbreviations and acronyms	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  IMDG: International Maritime Code for Dangerous Goods  IATA: International Air Transport Association  GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances  CAS: Chemical Abstracts Service (division of the American Chemical Society)  DNEL: Derived No-Effect Level (UK REACH)  LC50: Lethal concentration, 50 percent  LD50: Lethal dose, 50 percent  PBT: Persistent, Bioaccumulative and Toxic  vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
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: 314	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** 

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