

# CYTOGNOST KIT

The kit contains:

Hayem's solution

Tuerk's solution

ThromboGnost solution



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Trade name:	HAYEM'S SOLUTION					
Product code:	HY-OT-X**	Date of compilation:	06 December 2023	Version: 6	5	

SECTI	ON 1: Identification of the	substance/mix	ture a	nd of the company/undertaking		
1.1.	Product identifier					
	Trade name:	HAYEM'S SOLUTION				
	Chemical name:	-				
	Catalogue number:	HY-OT-X**				
1.2.	Relevant identified uses	Relevant identified uses of the substance or mixture and uses advised against				
	Uses:		Solution	on for manual counting of erythrocytes in microscopy.		
	Uses advised against:		Only t	he identified uses are advised.		
	Reason why uses advised	d against:	roduct is intended for use only as an <i>in vitro</i> diagnostic al device, registered at the Agency for Medicinal Products ledical Devices and there is no reason to use it for other ses.			
1.3.	Details of the supplier of the safety data sheet					
	Supplier:	BioGnost				
	Address:	Medjug	gorska	59, Zagreb		
	Telephone number:	+385 1	24099	97		
	Telefax:	+385 1 24040		39		
	e-mail of competent per	erson: <u>msds@biogno</u>		gnost.hr		
	National contact:	-				
1.4.	Emergency telephone nu	ımber				
	National Protection and	Rescue Directora	ite:	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 Regulation (EC) No 1272/2008 (CLP)						
	Hazard class and category code: Hazard statement*:						
	Acute Tox. 4	H302					
2.1.2.	Additional information						
	-	-					
* For fu	ıll text of Hazard- and EU Hazard-statements:	see SECTION 16					
2.2.	Label elements						
	Product identification: HAYEM'S SOLUTION						
	Identification number:	-					



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	Authorisation number:	-
	Hazard pictograms:	GHS07
	Signal word:	Warning
	Hazard statement:	H302 Harmful if swallowed.
	Precautionary statement:	P280 Wear protective gloves/protective clothing/eye/protection/face protection P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/ P308+P313 IF exposed or concerned: Get medical advice/attention.
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	Endocrine Disrupting Properties:	
	No known endocrine disrupting properties.	

SECTION 3. Composition/information on ingredients							
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)			
7487-94-7 231-299-8 080-010-00-X	-	0.25 %	mercuric chloride	Acute Tox. 2; H300 Skin Corr. 1B; H314 Muta. 2; H341 Repr. 2; H361f STOT RE 1; H372 Aquatic Acute 1;H400 Aquatic Chronic 1;H410			

SECTION	SECTION 4. First aid measures				
4.1.	Description of first aid measures				
	General notes:	Consult a physician. Show this safety data sheet to the doctor in attendance.			
	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.			



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	Following skin contact:  Following eye contact:  Following ingestion:  Self-protection of the first aider		Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.	
			Rinse out with plenty of water for at least 15 minutes with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.	
			Provide the afflicted person with water to rinse mouth. Do not induce vomiting. If vomiting occurs, keep the afflicted person's head in low position in order to prevent aspiration. If the symptoms remain, immediately call a physician.	
			Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.	
4.2.	Most important symptoms	and effe	cts, both acute and delayed	
	Following inhalation:	May cause respiratory tract irritation. Breathing Mercuric Chloride can irritate the lungs causing coughing and/or shortness of breath. Higher exposures can cause a build-up of fluid in the lungs (pulmonary edema).		
	Following skin contact:	May o	cause irritation. May be absorbed through the skin in harmful ints.	
	Following eye contact:	May cause irritation, redness, pain and tearing.		
	Following ingestion:	May cause irritation of the digestive tract. May be harmful if swallowed. Mercuric Chloride may cause liver and kidney damage.		
4.3.	Indication of any immediate	e medica	al attention and special treatment needed	
	No information available			

SECTION	SECTION 5. Firefighting measures				
5.1.	Extinguishing media				
	Suitable extinguishing media:	Water spray, alcohol-resistant foam, dry chemical or CO <sub>2</sub>			
	Unsuitable extinguishing media:	No information available			
5.2.	Special hazards arising from the substance or mixture				
	Hazardous combustion products:	Sulphur oxides, sodium oxides.			
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				
	Do not contaminate the environment with extinguishing media.				

SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	



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6.1.1.	For non-emergency personnel			
	Protective equipment:	Use personal protective equipment (see Section 8).		
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. 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	e 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 conta	inment 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			

SECTIO	SECTION 7. Handling and storage					
7.1.	Precautions for safe handling					
7.1.1.	Protective 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 incompatibilit	ties				



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

SECTION 8. Exposure controls/personal protection									
8.1. Con	trol para	imeters							
Substance		CAS No		Occupational exposure limit values/short term values		Biological limit values			
					ppm	r	ng/m³	-	
mercuric chlo	oride		7487-9	4-7	-		0,02	No	information available
Substance:	-								
EC No: -			CAS No: -						
DNEL									
					Industrial				
Route of exp	ocura.	Acu	te effect	Acute effect		Chronic effect		ct	Chronic effect
Noute of exp	osui e.		local	systemic		local			systemic
Oral		-		-		-			-
Inhalation		-		-		-			-
Dermal -		-		-		-			-
Critical physical parameters: solubility, flammability, corrosivity:									
					Consumer				



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Route of 6	exposure:	Acute effect local		cute effec systemic	t	Chronic effect local	Chronic effect systemic
Oral		-	-			-	-
Inhalation		-	-			-	-
Dermal		-	-			-	-
PNEC	PNEC						
Environme	Environmental protection target				NEC		
Fresh wat	er			N	o infor	mation available	
Freshwate	r sediment	S		N	o infor	mation available	
Marine wa	ater			N	o infor	mation available	
Marine se	diments			N	o infor	mation available	
Food chai	n			N	o infor	nation available	
Microorga	anisms in se	wage treatment		N	o infor	mation available	
Soil (agric	ultural)			N	o infor	mation available	
Air				N	o infor	mation available	
8.2.	Exposur	e controls					
8.2.1.	Appropr	iate engineering co	ntrols				
	measure	ce/mixture related es to prevent exposu dentified uses:	ıre	protecti	e the product in well ventilated rooms. Use personal otective equipment. Do not eat, drink or smoke in the orkspace.		
	Structur	al measures to prev e:	ent	No information available			
	Organisa exposur	ational measures to e:	prevent			f work in order to redu g work process.	ce other worker's
	Technica exposur	al measures to preve e:	ent			workspace ventilation i levels in air below pern	•
8.2.2.	Persona	protection equipm	ent:				
8.2.2.1.	Eye and	face protection:	Safety	glasses tl	nat stic	k to face (EN166) or vis	or.
8.2.2.2.	Skin pro	tection:					
	Hand pr	otection:	Protective gloves for long-time work (over 8 h) made of following materials: - polychloroprene, 0.5 mm, - nitrile rubber, 0.35 mm, - butyl rubber, 0.5 mm, - polyvinyl chloride, 0.5 mm.				



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	Other skin protection:		Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves, and shoes that cover the entire foot.		
8.2.2.3.	Respiratory protection:		Use a protective mask or a half mask with A-P3 combined filter (brownwhite).		
8.2.2.4.	Thermal hazards:	No info	ormation available		
8.2.3.	Environmental exposure co	ntrols			
	Substance/mixture related measures to prevent expos	ure:	See Section 6		
	Structural measures to prevexposure:	/ent	Use modern equipment.		
	exposure: 1  Technical measures to prevent		Adapt the work process to the required working conditions of the workplace.		
			See Section 6		

9.1.	Information on basic physical and	chemical properties	
		Value	Method
	Physical state:	Liquid	No information available
	Colour:	Colorless	No information available
	Odour/odour threshold:	Odourless/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 noctanol/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



Aspiration hazard:

No information available

# **SAFETY DATA SHEET** BIOGNOST® According to Regulation (EC) No 1907/2006 amended by Regulation (EU) No. 2020/878

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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:	No information available					
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:	Light.					
10.5.	Incompatible materials:	Strong oxidizing agents, strong bases.					
10.6.	Hazardous decomposition products:	Sodium oxides, sulfur oxides.					

11.1.	Information	tion on toxicological effects							
	Acute tox	icity:							
Route c		Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixtu</sub>	Exposure 1	time Results			
Oral:		No information available	-	No information available	-	No information available			
Dermal:		No information available	-	No information available	-	No information available			
Inhalati	on:	No information available	-	No information available	-	No information available			
	1				·	,			
	Specific ta	arget organ toxicity –	- single expos	ure (STOT SE):					
	Specific effects		Ta	arget organ	Note				
Oral:		No information av	on available			-			
Dermal	:	No information av	ailable	-	-	_			
Inhalation: No information available			_	-	_				



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			Exposure time	Species	Evaluation	Method	Note			
Skin corrosion/irrita	tion	-		-	-	-	No information available			
Serious eye damage/irritation		-	,	-	-	-	No information available			
Sensitizatio										
Skin sensitization:	)	No infe	ormation available							
Respiratory sensitiza	ation:	NO INTO	ormation available							
Symptoms	related to	the phys	sical, chemical and t	toxicological cl	naracteristics					
Oral exposure:			swallowed.							
Dermal exposure:	N	1ay cause	irritation. May be l	harmful if abso	orbed through	skin.				
Inhalation exposure		lay be harmful if inhaled. May cause respiratory tract irritation.								
Eye exposure:	lr	ritation a	ition and swelling may occur after direct contact with eyes.							
	:									
Repeated o	dose toxici	ty (subac	ute, subchronic, ch	ronic)						
,	Do	se	Exposure time	Species	Method	Evaluatio	n Note			
Subacute oral	No infor		No information available	No information available	No information available	No informatio available	n -			
Subacute dermal	No infor		No information available	No information available	No information available	No informatio available	n -			
Subacute inhalation	No infor		No information available	No information available	No information available	No informatio available	n -			
Subchronic oral	onic oral No information available		No information available	No information available	No information available	No informatio available	n -			
Subchronic dermal No information available			No information available	No information available	No information available	No informatic available	on -			
Subchronic inhalation	No infor		No information available	No information available	No information available	No informatic available	n -			



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Trade name:			HAYEM'S SOL	LUTION				
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Chronic oral	No information available	No information available	No information available	No information available	No informa availab		_	
Chronic dermal	hronic dermal No information available		No information available	No information available	No informa availab		-	
Chronic inhalation  No information available		No information available	No information available	No information available	No informa availab		-	
Specific to	rget organ toxicity	- reneated evnosi	Ira (STOT RE)					
Specific tal		ecific effects		arget organ		N	Note	
Subacute oral		tion available		ation available		-		
Subacute dermal		tion available		ation available		_		
Subacute inhalation	No informa	tion available	No informa				-	
Subchronic oral	No informa	ntion available No in		No information available				
Subchronic dermal	No informa	tion available	nation available -					
Subchronic inhalation	on No informa	tion available	No informa	ation available		-		
Chronic oral	No informa	tion available	e No information available -			-		
Chronic dermal	No informa	tion available	No information available -			-		
Chronic inhalation	No informa	tion available	No informa	ation available		-		
CMR effect	ts (carcinogenicity;	mutagenicity; rep	roductive toxicit	ty)				
Carcinoger	nicity:	1	ARC: Group 3: N	Not classified as	carcino	genic to I	numans.	
Mutagenic	ity in-vitro:		No information	available				
Genotoxici	ty:	1	No information available					
Mutagenic	ity in-vivo:		No information available					
Germ cell r	mutagenicity:		No information available					
Reproduct	ive toxicity:	1	No information	available				
Summary properties;		of the CMR I	No information	available				
11.2. Informatio	n on other hazards	:						
11.2.1. Endocrine	disrupting properti	es:						
No known	endocrine disrupti	ng properties that	t affect human h	nealth.				
11.2.2. Other info	rmation:							



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SECTION 12. E		Intormat	ion					
12.1. Toxicit	У							
Acute (short-te toxicity	rm)	Dose	Exposur e time	Species	Method		Evaluation	Note
Fish:		LC <sub>50</sub>	96 hours	No information available	No informa available		No information available	-
Crustacea:		EC <sub>50</sub>	48 hours	No information available	No informa available		No information available	-
Algae/aquatic μ	olants:	IC <sub>50</sub>	72 hours	No information available	No informa available		No information available	-
Other organism	ns:	-	-	No information available	No informa available		No information available	-
Chronic (long-t toxicity	erm)	Doza	Exposur e time	Species	Method		Evaluation	Note
Fish:		LC <sub>50</sub>	96 hours	No information available	No informa available	tion	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 informa available	tion	No information available	-
Other organisms: -		-	-	No information available	No informa available	tion	No information available	-
	ence and		ility					
Abiotio	c degradat	tion					:	
	Deg	radation l	nalf-lives	Metho	od		Evaluation	Note
Marine water	No info	rmation a	vailable	No information	available	No avai	information lable	-
Fresh water	No info	rmation a	vailable	No information	available	No avai	information lable	_



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Air	No inforn	nation avail	able	No information available		ble No informa		nation	-		
Soil	No inforn	nation avail	able	No	information	availabl	e No	inforr ailable	nation	_	
Biodeo	gradation										
% Degradatio		Time (days)		N	1ethod	E	valuation			Note	
No information available	No inf	No information N			No information N		No information available		No information available		
Octano Value	umulative pol-water par	rtition coef	ficient (	(log Kow	) Metho	od	Eva	aluation		Note	
No information available		ormation	-	-	No infor available	mation	No availabl	informatio e	n _		
Biocor	ncentration	factor (BCF)	)	:	1		:				
Value		Species		l	Method		Evaluatio	n		Note	
No information available	No inf availal	ormation ole			ormation ble		nformatio lable		infor ailable	mation	
Chron	ic ecotoxicit	Ту									
Value		Dose		oosure ime	Species		Method	Evaluation		Note	
Chronic toxicity on fish		LC <sub>50</sub>	No infor avail	mation able	No informa available	tion i	No nformati on available	No informati available	on	-	
Chronic toxicity on crustacea (Daphnia)		EC <sub>50</sub>	No infor avail	mation able	No informa available		No		on	-	



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					1		· · · · · · · · · · · · · · · · · · ·			1
								on available		
12.4.	Mobili	ity in	soil							
	Knowr	n or p	redict	ed distributi	on in environmen	ital c	ompartment	ts:		
	No inf	orma	ation a	vailable						
	Surfac	e ten	sion:							
	Va	lue		°C	Concentration	n	Me	ethod		Note
	No inform availal			o formation vailable	No informatio	n	No informa available	rmation		
	Adsor	ption	/desoi	rption	***					
Transpo	ort		-	efficient constant	log Kow	Εν	aporation ra	ate Met	hod	Note
Soil-Wa	ater		nform lable	ation	No information available			n No infori available		-
Water-A	۹ir		nform lable	ation	No information available	tion No information		n No infor		-
Soil-Air			nform lable	ation	No information available		o informatior ailable	n No infori available		-
					:	-		!		3
12.5.	Result	s of F	PBT an	d vPvB asses	ssment					
			-		mponente koje se o bioakumulirajud				•	
	1		-	<u> </u>			<u> </u>	<u> </u>		
12.6.	Endoc	rine o	disrupt	ting propert	ies					
	57(f), p	oropi	sa o R	egistraciji, o	_	avar	nju i ograniča	avanjju kemika	ılija (REA	upcije prema članku CH), ili delegiranoj ili više.
12.7.	Other	adve	rse eff	ects						
	No inf	orma	ation a	vailable						

#### **SECTION 13. Disposal considerations**

13.1. Waste treatment methods



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13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Low:
	15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances.
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

<b>SECTION 14. Transport informatio</b>	SECTION 14. Transport information					
Transporting/shipment by re	Transporting/shipment by road (ADR)					
UN number:	Not subject to transport regulations.					
UN proper shipping name:	-					
Transport hazard class(es):	-					
Packing group:	-					
Environmental hazards:	-					
Special precautions for user:	-					
Transporting/shipment by r	ail (RID)					
UN number:	Not subject to transport regulations.					
UN proper shipping name:	-					
Transport hazard class(es):	-					
Packing group:	-					



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Environmental hazards:	-				
Special precautions for user:	-				
Transporting/shipme	t by inland waterways (ADN)				
UN number:	Not subject to transport regulations.				
UN proper shipping name:	-				
Transport hazard class(es):	-				
Packing group:	-				
Environmental hazards:	-				
Special precautions for user:	-				
Transporting/shipme	t by sea (IMDG)				
UN number:	Not subject to transport regulations.				
UN proper shipping name:	-				
Transport hazard class(es):	-				
Packing group:	-				
Environmental hazards:	-				
Special precautions for user:	-				
Transport in bulk according of MARPOL73/78 and the IBC					
Transporting/shipme	t by air (ICAO-TI/IATA-DGR)				
UN number:	Not subject to transport regulations.				
UN proper shipping name:	-				
Transport hazard class(es):	-				
Packing group:	-				
Environmental hazards:	-				
Special precautions for user:	-				
	·				
Further information: The	Further information: The product is not subject to classification.				

SECTIO	SECTION 15. Regulatory information			
15.1.	Safety, health and env	Safety, health and environmental regulations/legislation specific for the substance or mixture		
	EU regulations			
	Authorisations and/or restrictions on use			
	Authorisations:	-		
	Restrictions:	-		



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Product code:	HY-OT-X**	Date of compilation:	06 December 2023	Version: 6

	None	
15.2.	Chemical safety assessme	ent
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Transport of Hazardous Substances Act
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	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);

SECTIO	SECTION 16. Other information				
16.1.	Indication of changes:	-			
16.2.	Abbreviations and acronyms:	PBT $vPvB$ $LD_{50}$ $LC_{50}$ STOT-SE	Stable, bioaccumulative and toxic Strongly stable and strongly bioaccumulative Lethal dose, 50% Lethal concentration, 50% Specific target organ toxicity – single exposure		
16.3.	Key literature references and source of data:	-			
16.4.	4. Classification and procedure used to derive the 1272/2008 (CLP)		classification for mixture according to Regulation (EC)		
Classification Clas		Classification proc	ssification procedure		
		_			
16.5.	5. Relevant H statements (number and full text)				



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	H:	300 302 314 341 361f 372 400 410	Fatal if swallowed. Harmful if swallowed. Causes severe skin burns and eye damage. Suspected of causing genetic defects. Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
16.6.	Training advice:		-
16.7.	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	
_	



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

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Trading name:	TUERK'S SOLUTION			
Product code:	TU-OT-X**	Date of compilation: 14 November 2022	Version: 5	

SECTI	ON 1: Identification of	the substance	e/mixture a	and of the company/undertaking		
1.1.	Product identifier					
	Trading name:	TUERK'S SC	LUTION			
	Chemical name:	-	-			
	Catalogue number:	TU-OT-X**				
1.2.	Relevant identified us	es of the subs	tance or mi	xture and uses advised against		
	Uses:		Solution f	or manual counting of leukocytes.		
	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: B		ioGnost Ltd.			
	Address: N		Medjugorska 59, Zagreb			
	Telephone number:		+385 1 2409997			
	Fax no.:		+385 1 2404039			
	e-mail of competent person: r		msds@biognost.hr			
	National contact: -					
1.4.	Emergency telephone number					
	National Protection and Rescue Dire		ectorate:	112		
	inational Protection ar	ia nescae Dire				
	Medical information:	na Rescue Din		+385 1 2348 342		

SECTIO	ON 2. Hazards identification			
2.1.	Classification of the substance or mixture			
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)			
Hazard class and category code:  Not identified as hazardous substance.  Hazard statements*:			Hazard statements*:	
			-	
2.1.2.	Additional information			
	-			
*For fu	ll text of Hazard- and EU Hazard-	-statements: see S	ection 16	
2.2.	Label elements			
	Product identification:	TUERK'S SOL	UTION	
	Identification number:	-		
	Authorization no.:	-		
	Hazard pictograms:	-		



**Endocrine Disrupting Properties:** 

No known endocrine disrupting properties.

# SAFETY DATA SHEET

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

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Trading name:		TUERK'S SOLUTION							
Product code: TU-OT-X**		Date of compilation:	14 November 2022	Version: 5					
Signal v	word:	-							
Hazard	statements:	-							
Precaut	ionary statements:	-							
Supple (EU):	metal hazard information	-							
2.3. Other h	nazards								

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

SECTIO	CTION 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 ai	er: Treat symptomatically.						
4.2.	Most important symptoms a	nd effects, both acute and delayed						
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.						
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Longterm exposure may cause drying, cracking and tingling sensation of skin.						
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.						



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

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



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

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 generati	on:	Secure proper ventilation.			
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.			
	Other measures:		-			
7.1.2.	Advice on general occupational hygiene:					
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.					
7.2.	Conditions for safe storage, including any incompatibilities					
	Technical measures and storage conditions:	vent	p in tightly closed and upright set containers in a well tilated storage rooms, and away from sources of heat, light, and other incompatible substances.			
	Packaging materials:	Mar	nufacturer's original packaging.			
	Requirements for storage rooms and vessels:		p away from food and drink. Keep the containers tly 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:	and che	not place the unused material in the storage room do not use empty containers for storing other micals. Do not store with incompatible materials (see tion 9).			



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<b>D</b>	1								
Recommer					-				
Industrial s	ector spe	cific solutio	ns:		-				
SECTION 8. Exposu	ire contro	ols/persona	al protec	tion					
8.1. Control pa	rameters								
				Occi	upational e	xposure limit			
Substance		CAS I	No	val	ues/short	term values	Biolo	gical limit values	
				I	ppm	mg/m³			
-		-			-	-	No informa	tion available	
i .									
Substance - name:									
EC No: -		CAS No:	-						
DNEL									
				Inc	lustrial				
		Acute Acute		e Chronic		ic	Chronic		
Route of exposure:		ct local effect sys			effect local		effect systemic		
Oral -			-			-			
Inhalation -		-				-	-		
Dermal	-	-					-		
Critical physical para	ameters: s	solubility, fla	ammabilit	ty, cor	rosivity:	-			
				Co	nsumer				
Route of exposure:	A	Acute Acut		e	Chronic		Chronic		
Noute of exposure.	effe	ect local	t local effect sys		temic	effect local		effect systemic	
Oral	-		-			-			
Inhalation	-		-			-			
Dermal		-			-				
PNEC									
Environmental protection target				PNEC					
Fresh water				No information available					
Freshwater sediments				No information available					
Marine water						nation availabl			
Marine sediments				No information available					
Food chain				No information available					
Microorganisms in s	sewage tr	eatment			No information available				
Soil (agricultural)				No information available					



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Air			No information available			
8.2.	Exposure controls					
8.2.1.	Appropriate engineering controls					
	Substance/mixture related measures to prevent expo		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to pr exposure:	event	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 prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equip	ment				
8.2.2.1.	Eye and face protection:		Safety glasses that stick to face (preventing splashing) (EN 166) or visor.			
8.2.2.2.	Skin protection					
			ective gloves must be according to the EU Directive 2016/425/EEC and dard EN 374.			
	Hand protection:		Glove material: nitrile rubber			
			Glove thickness: ≥0.50 mm			
		\ <b>\</b> \\	Break through time: >480 min			
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) with long es (EN 13034), and shoes that cover the entire foot (EN 10335).			
8.2.2.3.	Respiratory protection:	filter fo	ctive full face mask (EN 136) or half mask (EN 140) equipped with a for 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	formation available			
8.2.3.	Environmental exposure	controls				
	Substance/mixture related measures to prevent expo		See Section 6			
	Structural measures to pr exposure:	event	Use modern equipment.			
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.			
	Technical measures to proexposure:	event	See Section 6			

# **SECTION 9. Physical and chemical properties**



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Product code:	TU-OT-X**	Date of compilation: 14 November 2022	Version: 5		

	Value	Method
Physical state:	liquid	No information available
Color:	blue purple	No information available
Odour/odour threshold:	acetic acid like/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
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

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.			

# **SECTION 11. Toxicological information**



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Acute toxici	ty:					
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure t	ime	Results
Oral exposure:	No information available	-	LD <sub>50</sub>	-		-
Dermal exposure:	No information available	<del>-</del>	LD <sub>50</sub>	-		-
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-		-
Specific targ	get organ toxicity – s	ingle exposure (	STOT SE):			
	Specif	ic effects	Target	organ		Note
Oral exposure:	No information	available	No information	on available	-	
Dermal exposure:	No information	available	No information	on available	_	
Inhalation exposure:	No information	available	No information	on available	_	
Irritation an	d corrosion:					
Irritation an	d corrosion:  Exposure time	Species	Evaluation	Method	1	Note
Irritation an Skin irritation:		Species -	Evaluation -	Method 	1	Note
		Species - -	Evaluation - -		1	Note
Skin irritation:	Exposure time	-	-		1	Note
Skin irritation: Eye irritation: Sensitization	Exposure time	-	-		1	Note
Skin irritation:  Eye irritation:  Sensitization  Dermal exposure:	Exposure time	- - lable	-		<u> </u>	Note
Skin irritation:  Eye irritation:  Sensitization  Dermal exposure:  Inhalation  exposure:	Exposure time No information avai	- lable	-		ľ	Note
Skin irritation:  Eye irritation:  Sensitization  Dermal exposure:  Inhalation exposure:  Symptoms r	Exposure time  No information avai	lable lable	-		ľ	Note
Skin irritation:  Eye irritation:  Sensitization  Dermal exposure:  Inhalation exposure:  Symptoms r  Oral exposure:	Exposure time  No information avai No information avai	lable lable al, chemical and vailable	-			Note
Skin irritation:  Eye irritation:  Sensitization  Dermal exposure:  Inhalation  exposure:	Exposure time  No information avai No information avai related to the physical	lable lable al, chemical and vailable	-			Note



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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	<b>-</b>



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Chronic	inhalation	No informa	tion available	No information available	-		
	CMR effects (	carcinogenicity	r; mutagenicity; repr	roductive toxicity)			
	Carcinogenic	ity:	Current studies	on test animals did not indicate ca	rcinogenic effects.		
	Mutagenicity	in-vitro:	Current in vitr	o tests did not indicate mutageni	c effects.		
	Genotoxicity:		No information	n available			
	Mutagenicity in-vivo:		Current <i>in viv</i>	Current in vivo tests did not indicate mutagenic effects.			
	Germ cell mu	tagenicity:	No information available				
	Reproductive toxicity:  No toxicity organs.			n reproductive organs was deter	mined in reproductive		
	Summary of e	evaluation of th	ne CMR properties:	-			
11.2.	Information o	on other hazard	ls:				
11.2.1.	Endocrine dis	rupting proper	ties:				
	No known en	docrine disrup	ting properties that	affect human health.			
11.2.2.	Other informa	ation:	·				
	-						

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	-	-	-	-	
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note	
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-	
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-	



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Product code:		Т	TU-OT-X** D		Date	Date of compilation: 14 November		4 November	2022	Ve	rsion:	5
Algae/aquatic plants		ants	IC <sub>50</sub>	72 houi	ırc			No information available No information avail		mation able	-	
Other organisms		-	-		_	-		-		-		
12.2.			nd degradal	oility								
	Abiotic										-	
		Deg	radation hal	f-lives		Method		Eν	/aluatio	on		Note
Marine water	N	No inf	ormation av	ailable	No i	nformation availa	ble	No informa	tion av	vailable	-	
Fresh wa	iter N	lo inf	ormation av	ailable	No i	nformation availa	ble	No informa	tion av	vailable	-	
Air	N	lo inf	ormation av	ailable	No i	nformation availa	ble	No informa	tion av	ailable	-	
Soil	١	lo inf	ormation av	ailable	No i	nformation availa	ble	No informa	tion av	vailable	-	
	Biodegr	adatio	on									
% Degra	adation		Time (day	s)	Method			Evaluation		Note		
No infor available		No								No infor		
avaliable		ava	шаріе		available		av	available ava		available	validore	
12.3.	Bioaccu	mulat	tive potentia	ı								
			er partition c		(log l	(ow)						
Value			ntration	рН	°C	Method		Evaluati	ion		Note	<u> </u>
-	No ava	in ailable	oformation	-	_	No information	on	No information - available				
		-										
						1		!		<u> </u>		
	Bioconc	entra	tion factor (	BCF)								
Va	lue		Specie	es		Method		Evaluation	1		Note	
No information available		No information available					No information available		No information available			
	Chronic	ecoto	oxicity									
			-									



No adverse effects are expected.

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Produc	ct cod	e: TL	J-OT-X**	Date of co	ompilat	tion: 14	Novembe	er 2022	Vers	ion: 5
	Val	ue	Dose	Exposure time	Spec	ies N	Method	Evaluat	ion	Note
Chronic toxicity on fish		LC <sub>50</sub>	information	No informa availab	1	rmation lable	No information available	on	-	
Chronic crustac		-	EC <sub>50</sub>	information	No informa availab	1	rmation lable	No information available	on	-
12.4.	Mob	ility in soi	l							
	Knov	vn or prec	dicted distributi	on in environme	ental co	mpartment	s:			
	No ir	nformatio	n available							
	Surfa	ce tensio	n:							
	V	'alue	°C	Concentrati	ion	Me	thod		No	ote
	No infor avail	mation able	No information available	No information available		No information available		-		
	Adsc		lesorption	İ	1					
Transpo	ort		coefficient 's constant	log Kow	Eva	poration rat	te N	1ethod		Note
Soil-wa	ter	No available	information	No information available		information lable	No int	formation ble	-	
Water-a	air	No available	information			lo information No ir vailable availa		formation ble	-	
Soil-air		No available	information	No information available		information lable	No inta	formation ble	-	
12.5.	Resu	Its of PBT	and vPvB asses	ssment						
	No ir	nformatio	n available							
12.6.	Endo	ocrina dicr	upting properti	ios						
12.0.				ng properties th	at affor	t the onviro	nment			
	INO K	HOWIT END	iocinie distupti	ng properties th	iat allec	it the enviro	minient.			
12.7.	Othe	er adverse	effects							
	Ciri		311000							



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SECTION	SECTION 13. Disposal considerations					
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.					
13.1.2.	Waste codes/waste designation	ons according to Law:				
	No information available					
13.1.3.	Waste treatment – relevant in	formation:				
	No information available					
13.1.4.	Sewage disposal – relevant inf	formation:				
	Waste must not be disposed of	of into the sewage system.				
13.1.5.	Other disposal recommendati	ons:				
	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 provision	ns:				
	-					
SECTION	14. Transport information					
-	Transporting/shipment by road	(ADR)				
UN numb	per:	Not subject to transport regulations.				
UN prope	er shipping name:	-				
Transport hazard class(es):		-				
Packing group:		-				
Environmentally hazardous:		-				
Special precautions for user:		-				
-	RID)					
UN numb	per:	Not subject to transport regulations.				
UN prope	er shipping name:	-				
		ı.				



Trading name:

#### **SAFETY DATA SHEET**

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

**TUERK'S SOLUTION** 

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Product code:	TU-OT-X**	Date of compilation:	14 November 2022	Version: 5			
Transport hazard	class(es):	-	-				
Packing group:		-					
Environmentally h	azardous:	-					
Special precaution	ns for user:	-					
Inland wa	aterway transport (A	ADN)					
UN number:		Not subject to transport	regulations.				
UN proper shippii	ng name:	-					
Transport hazard	class(es):	-					
Packing group:		-					
Environmentally h	azardous:	-					
Special precaution	ns for user:	-					
Transpor	ting/shipment by se	ea (IMDG)					
UN number:		Not subject to transport	regulations.				
UN proper shippi	ng name:	-					
Transport hazard	class(es):	-					
Packing group:		-					
Environmentally h	azardous:	-					
Special precaution	ns for user:	-					
Transpor	ting/shipment by ai	r (ICAO-TI/IATA-DGR)					
UN number:		Not subject to transport regulations.					
UN proper shippiı	ng name:	-					
Transport hazard	class(es):	-	-				
Packing group:		-					
Environmentally hazardous:		-					
Special precaution	ns for user:	-					
Further information	on: The produ	ct is not subject to classificatio	n.				

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



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Trading name:	TUERK'S SOLUTION			
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	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (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;	
		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-quideline)		
	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 assessmen	nt	
	None		

SECTIO	ON 16. Other information			
16.1.	Indication of changes:	-		
		PBT	Stable, bioaccumulative and toxic	
		vPvB	Strongly stable and strongly bioaccumulative.	
16.2.	Abbreviations and acronyms:	LD <sub>50</sub>	Lethal dose, 50%	
		LC <sub>50</sub>	Lethal concentration, 50%	
		STOT-SE	Specific target organ toxicity - single exposure	
16.3.	Key literature references and source of data:	-		
16.4.	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.	16.5. Relevant H statements (number			
	H: -	-		



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16.6.	Training advice:	-
		** "X" in the product code marks different volumes (different packagings of the product)
16.7.	Further information:	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	g to Chemical safety assessment
-	



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

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Trading name:	THROMBOGNOST SOLUTION				
Product code:	THR-OT-X**	Date of compilation:	03 April 2023	Version:	4

1.1	Product identifier				
	Trading name:	THROMBO	GNOST SC	DLUTION	
	Chemical name:	-			
	Catalogue number:	THR-OT-X*	THR-OT-X**		
1.2	Relevant identified us	es of the subs	tance or m	nixture and uses advised against	
	Uses:		Solution	for manual counting of thrombocytes.	
	Uses advised against:		Only the	identified uses are advised.	
	Reason why uses advised against: medical device, registered		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 sheet				
	Supplier: Address: Telephone number:		BioGnost Ltd.		
			Medjugorska 59, Zagreb		
			+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent p	person:	msds@biognost.hr		
	National contact:	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 F	Regulation (EC) No 12	272/2008 (CLP)	
	Hazard class and car	tegory code:	Hazard statements*:	
	Carc. 1B		H350	
2.1.2.	Additional information			
	-			
*For fu	Ill text of Hazard- and EU Haza	ırd-statements: see S	SECTION 16	
2.2	Label elements			
	Product identification:	THROMBOGNO	ST SOLUTION	
	Identification number:	-		
	Authorization number:	-		



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

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Trading name:	THROMBOGNOST SOLUTION				
Product code:	THR-OT-X**	Date of compilation:	03 April 2023	Version:	4

	Hazard pictograms:	GHS08	
	Signal word:	Danger	
	Hazard statements:	H350 May cause cancer.	
	Precautionary statements:	P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P308+P313 IF exposed or concerned: Get medical advice/attention. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P501 Dispose of contents/container according to local regulations.	
	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. 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)
50-00-0/ 200-001-8/ 605-001-00-5	01-2119488953-20- XXXX	<1%	formaldehyde, 40%	Carc. 1B; H350 Muta. 2; H341 Acute Tox. 3; H331 Acute Tox. 3; H311 Acute Tox. 3; H301 Skin Corr. 1B; H314 Skin. Sens. 1; H317

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.	



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Product code:	THR-OT-X**	Date of compilation:	03 April 2023	Version:	4			

	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of respiratory arrest, provide artificial respiration (while not exposing the provider). In case of unconsciousness, transport the afflicted person in the lateral position. Seeking medical advice is advised.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink at most 1-2 glasses of water. Do not induce vomiting. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and ef	fects, 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

SECTI	CTION 5. Firefighting measures					
5.1	Extinguishing media					
	Suitable extinguishing media:	Water spray, dry powder, CO <sub>2</sub> or alcohol resistant foam.				
	Unsuitable extinguishing media:	No information available				
5.2	Special hazards arising from the substance or mixture					
	Hazardous combustion products:	Formalin solution is not flammable in itself. Gases released from the solution are flammable if the concentration of the solution is >25%. In case of combustion carbon dioxide and carbon monoxide will be released, which are heavier than air. Vapours are heavier than air and may spread along the floors. Forms explosive mixtures with air on intense heating. Development of hazardous combustion gases or vapours possible in the event of fire.				



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Trading name:		THROMBOGNOST SOLUTION							
Product code:	THR-OT-X**	Date of compilation:	03 April 2023	Version:	4				

5.3	Advice for firefighters
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.
5.4	Additional information
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.

6.1	Personal precautions, protective	Personal precautions, protective equipment and emergency procedures						
6.1.1.	For non-emergency personnel							
	Protective equipment:	Use personal protective equipment (see Section 8).						
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.						
	Emergency procedures:	Mark the area using proper signs.						
6.1.2.	For emergency responders:							
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).							
6.2	Environmental precautions:							
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.							
6.3	Methods and material for cont	ainment and cleaning up						
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.						
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.						
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).						
6.4	Reference to other sections							
	See Section 7 for information	on safe handling.						
	See Section 8 for information	See Section 8 for information on personal protection equipment.						
	See Section 13 for disposal inf	ormation.						

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. Keep away from sources of ignition and heat.



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Trading name:		THROMBOGNOST SOLUTION							
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	Management and and all the analysis		C	
	Measures to prevent aerosol and dust generation	on:	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:	3 1 ,3		
	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 incom	npatibilities		
	Technical measures and storage conditions:		htly closed and upright set containers at res ranging from +15 to +25 °C.	
	Packaging materials:	Manufacturer's original packaging. Avoid metal containers.  Keep away from food and drink. Keep the containers tightly closed.		
	Requirements for storage rooms and vessels:			
	Advices for storage equipment:	must be re	e must be made of hard material; floors esistant to chemicals. There must be no drain ly leads into sewage system. Secure proper	
	Further information on storage conditions:	and do no	t use empty containers for storing other Do not store with incompatible materials on 10).	
7.3	Specific end use(s)	· 		
	Recommendations:	-		
	Industrial sector specific solutions:	_		

SECTION 8. Expos	ure contro	ols/perso	nal protec	tion				
8.1 Control pa	arameters							
Substance		CAS No			Occupational exposure limit values/short term values		Biological lin	nit values
				ppm		mg/m³		
Formaldehyde		50-00-0		2		2.5	-	
Substance name:	-							
EC No:	-	CAS No	: -					
DNEL								
	Industrial							
Route of	Route of Acute Acute		te		Chronic	Chi	ronic	
exposure:	effect	local	effect sy	stemic		effect local	effect s	systemic



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

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Trading r	name:		OLUTION						
Product	code:	THR-OT-X**		Date of	of compilation: 03 April		2023	Version:	4
Oral		-	-		-		-		
Inhalation	ı	0.75 mg/m <sup>3</sup> (formaldehyde)	-		0.375 mg/m <sup>3</sup> (formaldehyde	)	9 mg/m³ (formaldehyde)		(ڊ
Dermal		-	-		0.037 mg/cm <sup>2</sup> (formaldehyde	)	240 mg/kg (formaldehyde)		
Critical ph	nysical par	ameters: solubility,	flammab	oility, corr	osivity: -				
				Con	sumer				
Route of		Acute	А	cute	Chron	ic	(	Chronic	
<b>exposure:</b> effec		effect local	effect	systemic	effect lo	ocal	effe	ct systemic	
Oral		-	-		-		4.1 mg/kg	(formaldehyd	de)
Inhalation	1	-	-		0.1 mg/m <sup>3</sup> (formaldehyde)		3.2 mg/m <sup>3</sup>	(formaldehy	de)
Dermal		-	-		0.012 mg/cm <sup>2</sup> (formaldehyde)		102 mg/kg	(formaldehy	⁄de)
PNEC									
Environme	ental prot	ection target			PNEC				
Fresh water				0.44 mg/l (formaldehyde)					
Freshwate	Freshwater sediments				2.3 mg/kg (formaldehyde)				
Marine wa	ater				0.44 mg/l (formaldehyde)				
Marine se	diments				2.3 mg/kg (formaldehyde)				
Food chai	in				No information available				
Microorga	anisms in	sewage treatment		-	0.19 mg/l (formaldehyde)				
Soil (agric	cultural)			1	0.2 mg/kg (formaldehyde)				
Air					No information av	ailable			
8.2	Exposi	ure controls							
8.2.1.	Appro	priate engineering	controls	1					
		ince/mixture related at exposure during		es to	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.				
	Organ exposi	isational measures ure:	to prever		Organization of work in order to reduce other worker's influence during work process.				S
	Techni	cal measures to pre	event exp	NOSHIPE.	Secure proper wor concentration leve	•		•	
8.2.2.	Persor	nal protection equip	ment						



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8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN374.  Full contact:  Glove material: nitrile rubber  Glove thickness: 0.40 mm  Time until perforation: > 480 min  Splash contact:  Gloves material: polychloroprene  Glove thickness: 0.65 mm  Time until perforation: > 240 min
	Other body parts protection:	Complete suit protecting against chemicals (EN 340) The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Not required under normal conditions of use. Use suitable respiratory protective device when high concentrations are present.
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

SECT	SECTION 9. Physical and chemical properties						
9.1	Information on basic physical and chemical properties						
		Value	Method				
	Physical state:	liquid	Visual inspection				
	Colour:	dark blue - purple	Visual inspection				
	Odour/odour threshold:	No information available	No information available				
	Melting point / freezing point:	No information available	No information available				



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Tra	ding name:	THROMBOGNOST SOLUTION				
Pro	duct code:	THR-OT-X**	Date of compilation:	03 April 2023	Version:	4

	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 (room temperature).			
10.3	Possibility of hazardous reactions:	No dangerous reactions known.			
10.4	Conditions to avoid:	Sources of heat, sparks, ignition, and low temperature.			
10.5	Incompatible materials:	No information available			
10.6	Hazardous decomposition products:	No information available			

SECTION 11. To	SECTION 11. Toxicological information								
11.1 Informa	11.1 Information on toxicological effects								
Acute t	oxicity:								
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results				
Oral:	-	rat	LD <sub>50</sub>	No information available	100 mg/kg (formaldehyde)				
Dermal:	-	rabbit	LD <sub>50</sub>	No information available	300 mg/kg (formaldehyde)				



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Trading name:		THROMBOGNOST SOLUTION									
Product code: The		R-OT-X**		Date of c	ompilati	on:	03 Apri	il 2023		Version:	4
	·		·			:				:	
Inhalation:		_	rat		LD <sub>50</sub>			4 h		3 mg/ (formaldeh	
										(IOIIIIaiuei	iyue)
Specific	target	organ toxicit	y – single exp	posure (S	STOT SE):						
		Spec	ific effects			Target o	organ			Note	
Oral:	No	information	available		No infor	rmation a	available	e -	-		
Dermal:	No	information	available		No infor	rmation a	available	е -	_		
Inhalation:	No	information	available		No infor	rmation a	available	е -	_		
								-			
Aspiration	on haza	ırd:		No infor	mation av	ailable.					
Irritation	n and co	orrosion									
		Exposur	e time	Spec	ies	Evaluati	on l	Method		Note	
Skin		_		_	-	_	_		_		
corrosion/irritation	on:										
Serious eye	_	-		-	-	_	-		_		
damage/irritation	า				1						
Sensitiza	ation										
Skin sensitization	n:	-									
Respiratory sensi	tization	n: -									
		i									
Sympto	ms rela	ted to the pl	nysical, chem	ical and t	oxicologi	cal chara	cteristic	CS			
Oral exposure:			n concentrat ge, nausea, v		•	time, it r	nay lead	d to sting	ing an	d digestive	
Dermal exposure	٠.			ration and exposure time, redness accompanied by sensation of occur, as well as skin cracking and rash.					f		
Inhalation expos	irρ. :	Depending c and dyspnea		ration and exposure time, it may lead to mucosa irritation, cough,							
Eye exposure:			n concentrat	tion and	exposure	time, it r	nay lead	d to sting	ing, te	aring, and p	ain.
, ,					•	<u> </u>				<u> </u>	
Repeate	ed dose	toxicity (sub	acute, subch	ronic, chi	ronic)						
,		Dose	Exposure time	Speci	es	Method	d	Evaluati	on	Note	
Subacute oral	No i availa	nformation ble	No information available	No inforr availa	nation ble	No informa availab		No informa available		-	



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

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		Specific effec	rts	Target o	rgan	Note
Specific	target organ toxicit	y – repeated e	xposure (STOT	RE):		
Chronic inhalation	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 oral	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	-
Subchronic dermal	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	-
Subacute inhalation	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	-

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

	CMR effects (carcinogenicity; mutagenicity; re	productive toxicity)
	Carcinogenicity:	No information available.



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Trading name:		THROMBOGNOST S			
Product code:	THR-OT-X**	Date of compilation:	03 April 2023	Version:	4

	Mutagenicity in vitro:	No information available.
	Genotoxicity:	No information available.
	Mutagenicity in vivo:	No information available.
	Germ cell mutagenicity:	No information available.
	Reproductive toxicity:	No information available.
	Summary of evaluation of the CMR properties:	No information available.
11.2.	Information on other hazards:	
11.2.1.	Endocrine disrupting properties:	
	No known endocrine disrupting properties that affect human health.	
11.2.2.	Other information:	
	-	

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	Pimephales promelas	-	6.7 mg/l (formaldehyde)	-
Crustacea:	EC <sub>50</sub>	48 hours	Daphnia magna	-	5.8 mg/l (formaldehyde)	-
Algae/aquatic plants	IC <sub>50</sub>	4 days	algae	-	4.89 mg/l (formaldehyde)	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No informatio n available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No informatio n available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No informatio n available	No information available	-



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Trading name	•				THROMBOG	NOST	SOLUTION	
Product code: THR-OT-X**		Date of compilation: 03 April 2023		Wersion: 4				
							·	i
Other organism	ıs	-	-	-		-	-	-
12.2 Persist	ence	and degrada	bility					
Abiotic	deg	gradation						
	I	Degradation h	nalf-lives		Method		Evaluation	Note
Marine water   No intermation available		No ir avail	nformation able	No ir availa	nformation able	-		
Fresh water No information available		No ir avail	nformation able	No ir	nformation able	-		
Air No information available		No ir	nformation able	No ir	nformation able	-		
Soil No information available		No ir avail	nformation able	No ir availa	nformation able	-		
Biodeg	grada	ntion						
% Degradation Time (days)			Method		Evaluation	Note		
		No information					nformation	No information
available		available		available ava		availa	able	available
		lative potenti						
		ater partition				9 9 9 9		
Value	Value Concentration pH		°C Method E		Evaluation	Note		
			-	-	-		_	-
***								
		<u>-</u>						
:	cent	ration factor		×				
Value		Spec			Method		Evaluation	Note
No information available		No information available		No information available		No information available		-
Chroni	C eco	otoxicity						
Cilioni		JUNICITY						



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Trading name:		THROMBOGNOST	SOLUTION	<u> </u>	
Product code:	THR-OT-X**	Date of compilation:	03 April 2023	Version:	4

Produc	it code.	01-X	Date	e or compliant	011. 05	April 2025	version. 2
		;		:		:	
	Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic	toxicity on fish	LC <sub>50</sub>	No information available	No information available	No informati on available	No information available	-
Chronic toxicity on crustacea ( <i>Daphnia</i> )		EC <sub>50</sub>	No information available	No information available	No informati on available	No information available	-
12.4	Mobility in soil						
	Known or predic	ted distribut	ion in environm	nental compart	ments:		
	No information a	vailable					
	Surface tension:						

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

		Adsorption	/	desorption
--	--	------------	---	------------

		•				
Transport	A/D coeff Henry's co		log Kow	Evaporation rate	Method	Note
Soil-water	No inf available	formation	No information available	No information available	No information available	-
Water-air	No inf available	formation	No information available	No information available	No information available	-
Soil-air	No inf available	formation	No information available	No information available	No information available	-

#### 12.5. Results of PBT and vPvB assessment

No information available

#### 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.



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12.7.	Other adverse effects					
	No information available					
SECTION	N 13. Disposal considerations					
13.1	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
	Waste material must be disposed of according to the national and local rules and regulations. Do not mix with other sorts of waste. Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.					
13.1.2.	Waste codes/waste designations acco	rding to Law:				
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances					
13.1.3.	. Waste treatment – relevant information:					
	No information available					
13.1.4.	Sewage disposal – relevant information	on:				
	Waste must not be disposed of into the sewage system.					
	`					
13.1.5.	Other disposal recommendations:					
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.					
13.1.6.	Relevant Community provisions:					
	Directive 2009/98/EC on waste and repealing certain directives.					
	N 14 TRANSPORT INFORMATION					
<u>i</u>	Transporting/shipment by road (ADR)					
UN num		ubject to transport regulations				
	per shipping name: -					
······································	ort hazard class(es): -					
Packing						
	interitary nazaraous.					
special b	precautions for user: -					



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Trading name:		THROMBOGNOST S	OLUTION		
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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:	-
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 (II	MDG)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	3334
UN proper shipping name:	Aviation regulated liquid, n.o.s. (formaldehyde)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	None
Special precautions for user:	No information

### SECTION 15. Regulatory information

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



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

SECTION 16. Other information	
16.1 Indication of changes:	-



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16.2	Abl	oreviations 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	Classification		Classification procedure		
_	,		-		
16.5.	Relevant H statements (number and full text)		per and full text)		
		301+311+331	Toxic if swallowed, in contact with skin or if inhaled.		
		314	Causes severe skin burns and eye damage		
	H:	317	May cause allergic skin reaction.		
		341	Suspected of causing genetic defects.		
		350	May cause cancer.		
16.6.	Tra	Training advice: -			
			** "X" in the product code marks different volumes (different packagings of the product)		
16.7.			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