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

SECTI	ION 1: Identification of t	he substance	e/mixture	e and of the company/undertaking	
1.1	Product identifier				
	Trading name:	THROMBOO	GNOST SC	DLUTION	
	Chemical name:	-			
	Catalogue number:	THR-OT-X*	*		
1.2	Relevant identified use	es of the subst	tance or n	nixture and uses advised against	
	Uses:		Solution	for manual counting of thrombocytes.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses advised against: The product is intended for use only as an <i>in vitro</i> diagno device, registered at the Agency for Medicinal Products a Devices and there is no reason to use it for other purpose				
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 <u>msds@biognost.hr</u>		
	e-mail of competent p	erson:			
	National contact:		-		
1.4	Emergency telephone	Emergency telephone number			
	National Protection an	d Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ECTION 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*:	
	Carc. 1B		H350		
2.1.2.	Additional information				
	-				
*For ful	l text of Hazard- and EU Hazard-	statements: see S	ECTION 16		
2.2	Label elements				
	Product identification:	THROMBOGNO	ST SOLUTION		
	Identification number:	-			
	Authorization number:	-			



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	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			
	Results of PBT and vPvB asse PBT or a vPvB.	essment: According to the results of its assessment, this substance is not a		

SECTION 3. Co	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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	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

SECTIO	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Water spray, dry powder, CO ₂ or alcohol resistant foam.			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the su	ibstance 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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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.

SECTIO	ON 6. Accidental release meas	ures			
6.1	Personal precautions, protective 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. 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 con	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 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.			
		on personal protection equipment.			
	See Section 13 for disposal inf	ormation.			

SECTIO	SECTION 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat.			



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	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:		
	Do not eat, drink or smoke in the workspace. The	noroughly was	sh hands after work and before eating.
7.2	Conditions for safe storage, including any incon	npatibilities	
	Technical measures and storage conditions:		ghtly closed and upright set containers at ires ranging from +15 to +25 °C.
	Packaging materials:	Manufacturer's original packaging. Avoid metal containers. Keep away from food and drink. Keep the contain tightly closed.	
	Requirements for storage rooms and vessels:		
	Advices for storage equipment:	must be re	ge must be made of hard material; floors esistant to chemicals. There must be no drain Ily leads into sewage system. Secure proper n.
	Further information on storage conditions:	and do no	ace the unused material in the storage room it 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. Exposure controls/personal protection								
8.1 Control p	Control parameters							
Substance		CAS No			Occupational exposure limit values/short term values			Biological limit values
				рр	m	mg/m ³		
Formaldehyde		50-00-0		2		2.5		-
Substance name:	-							
EC No:	-	CAS No	: -					
DNEL								
Industrial								
Route of	Αcι	ıte	Acu	te		Chronic		Chronic
exposure:	effect	local	effect sy	stemic		effect local		effect systemic



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Oral		-	-		-		-		
Inhalation		0.75 mg/m ³ (formaldehyde)	-		0.375 mg/m ³ (formaldehyde	2)	9 mg/m ³ (f	ormaldehyde	e)
Dermal		-	-		0.037 mg/cm ² (formaldehyde)		240 mg/kg	(formaldehy	/de)
Critical phys	sical pa	rameters: solubility	, flammability, co	orros	sivity: -		·		
			C	ons	umer				
Route of exposure:		Acute effect local	Acute effect system	ic	Chroi effect l			Chronic ct systemic	
Oral		-	-		-		4.1 mg/kg	(formaldehy	de)
Inhalation		-	-		0.1 mg/m ³ (formaldehyde	e)	3.2 mg/m ³	(formaldehy	de)
Dermal		-	-		0.012 mg/cm ² (formaldehyde)		102 mg/kg	(formaldehy	/de)
PNEC					·				
Environmen	Environmental protection target			PNEC					
Fresh water				0.44 mg/l (formaldehyde)					
Freshwater	sedime	nts		2.3 mg/kg (formaldehyde)					
Marine wate	er			0.44 mg/l (formaldehyde)					
Marine sedi	ments			2.3 mg/kg (formaldehyde)					
Food chain				No information available					
Microorgan	isms in	sewage treatment		0.	19 mg/l (formal	dehyde)			
Soil (agricul	tural)			0.2 mg/kg (formaldehyde)					
Air				No information available					
8.2	Expos	ure controls							
8.2.1.	Appro	priate engineering	controls						
		ance/mixture relate nt exposure during		Use the product in well ventilated rooms. Use person protective equipment. Do not eat, drink or smoke in workspace.			•		
	Struct	ural measures to pi ure:	revent	In accordance with Section 7. Organization of work in order to reduce other wor influence during work process.					
	Organ expos	isational measures ure:	to prevent				ther worker'	S	
	Techn	ical measures to pr	event exposure:		ecure proper wo oncentration lev	•		•	
8.2.2.	Persor	nal protection equi	oment						



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8.2.2.1.	Eye a	nd 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						
	Othe	er 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.	Respi	ratory protection:	Not required under normal conditions of use. Use suitable respiratory protective device when high concentrations are present.					
8.2.2.4.	Thern	nal hazards:	No information available					
8.2.3.	Enviro	onmental exposure controls						
		ance/mixture related ures to prevent exposure:	See Section 6					
	Struc expos	tural measures to prevent sure:	t Use modern equipment.					
		nisational measures to nt exposure:	Adapt the work process to the required working conditions of the workplace.					
	Techr expos	nical measures to prevent sure:	See Section 6					

SECT	SECTION 9. Physical and chemical properties						
9.1	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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	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n- octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		

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. Toxicological information								
11.1 Informatio	1.1 Information on toxicological effects							
Acute toxic	Acute toxicity:							
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results			
Oral:	-	rat	LD ₅₀	No information available	100 mg/kg (formaldehyde)			
Dermal:	-	rabbit	LD ₅₀	No information available	300 mg/kg (formaldehyde)			



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Inhalation:		-	rat		LD ₅₀			4 h		3 mg, (formalde	
Specific	targe	t organ toxicit	y – single ex	posure (S	TOT SE):						
i •		Speci	ific effects			Target or	rgan			Note	
Oral:	٨	lo information	available		No infor	mation av	vailable	-			
Dermal:	٨	lo information	available		No infor	mation a	vailable				
Inhalation:	Ν	lo information	available		No infor	mation a	vailable	. –			
Aspiratio	on ha	zard:		No infor	mation av	ailable.					
Irritatior	n and	corrosion							1		
		Exposur	e time	Spec	ies	Evaluatio	n N	/lethod		Note	
Skin corrosion/irritatio	on:	-		-	-	-	-		-		
Serious eye	-			-	-	-	-		-		
damage/irritatior	า										
Sensitiza	ation										
Skin sensitization	n:	_									
Respiratory sensi	tizatio	on: -									
		:									
Sympto	ms re	lated to the ph	nysical, chen	nical and t	oxicologi	cal charac	teristic	S			
Oral exposure:		Depending o mucus dama			exposure	time, it m	ay lead	to stingi	ng and	d digestive	
Dermal exposure	:	Depending o stinging and			•			•	ed by s	sensation o	of
Inhalation exposi	ure:	Depending o and dyspnea	n concentra			_			sa irrit	ation, coug	gh,
Eye exposure: Depending on conc				tion and	exposure	time, it m	ay lead	to stingi	ng, tea	aring, and j	pain.
		. · ·			<u> </u>		-				
Repeate	ed dos	se toxicity (sub	acute, subcl	nronic, ch	ronic)						
		Dose	Exposure time	Speci	es	Method		Evaluatio	on	Note	
Subacute oral No information No information		No informatio available	No n inforr availa	nation ble	No informat available		No informat available		-		



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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 availabl		No information available	-
Subchronic dermal No information availa		ailable 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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				·····							
	Mutagenio	city <i>in vitro</i> :		No information available.							
	Genotoxic	ity:		No information a	available.						
	Mutagenio	city <i>in vivo</i> :		No information a	available.						
	Germ cell	mutagenicity:		No information a	available.						
	Reproduct	tive toxicity:		No information available.							
	Summary properties		CMR	No information available.							
11.2.	Informatio	on on other hazards:									
11.2.1.	Endocrine	disrupting properties:									
	No known endocrine disrupting properties that affect human health.										
11.2.2.	Other info	rmations:									
	-										

SECTION 12. Ecological information							
12.1 Toxicity							
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note	
Fish	LC ₅₀	96 hours	Pimephales promelas	-	6.7 mg/l (formaldehyde)	-	
Crustacea:	EC ₅₀	48 hours	Daphnia magna	-	5.8 mg/l (formaldehyde)	-	
Algae/aquatic plants	IC ₅₀	4 days	algae	-	4.89 mg/l (formaldehyde)	-	
Other organisms	-	-	-	-	-	-	
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note	
Fish	LC ₅₀	96 hours	No information available	No informatio n available	No information available	-	
Crustacea:	EC ₅₀	48 hours	No information available	No informatio n available	No information available	-	
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No informatio n available	No information available	-	



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Other	organism	S	-	-	-		-	-		-	
12.2	Dorcict	0000	and degrada	bility							
12.2			and degrada radation	Dility							
	ADIOLIC	-	Degradation h	alf-lives		Method		Evaluation		Note	
Marine	e water				formation		formation	-			
Fresh v	water	No information available		No in availa	formation ble	No ir availa	nformation able	-			
Air		No information available		No in availa	formation ble	No ir availa	nformation able	-			
Soil	No information available		No in availa	formation ble	No information available		-				
	1										
	Biodeg	rada	tion								
	% Degradation Time (days)			Method		Evaluation		Note			
	No information No information available available		formation			No information No available ava		rmation e			
12.3	Bioacci	umul	ative potentia	al							
	Octanc	ol-wa	ter partition o	coefficient (log Kov	N)					
Val	ue	Con	centration	рН	°C	Method		Evaluation		Note	
-	-				-	-		-	-		
	Biocon	cent	ration factor (BCF)							
,	Value		Speci			Method		Evaluation		Note	
No informationNoinformationavailableavailable		No information N			No information available						
	Chroni	c ecc	otoxicity								



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				1	;		:				1		
	Value		Dose	Exposure time	Spe	ecies	Method		Evaluation		Note	Note	
Chronic toxicity on fish LC ₅₀		No information available	No inforr availa	nation Ible	No informati on available		No informatior available		-				
Chronic toxicity on crustacea (<i>Daphnia</i>) EC ₅₀		No information available	No inforr availa	mation Ible	No informati on available		No information available		-				
12.4	Mobilit	y in soi	1										
12.4		-	ı dicted distributi	on in environm	nental c	ompart	mente						
		•	n available			ompart	incito.						
		e tensio											
	Val		°C	Concentration Method					Note				
	No No information information		No informa	No information No information				_					
	availab		available	available	available availabl		ole						
	Adsorp	otion / c	lesorption										
Transpo	ort		coefficient 's constant	log Kow	Εv	vaporati	on rate		Meth	od	Note		
Soil-wa	ter N	o /ailable	information	No informatio available		o inform ailable	nation	tion No information available		nation	-		
Water-a	air N av	o /ailable	information	No informatio available		o inform ailable	nation		o inforn ailable		-		
Soil-air	N av	o /ailable	information	No informatio available		o inform ailable	nation		o inforn ailable		-		
	1												
12.5.	Results	of PBT	and vPvB asses	ssment									
	No info	ormatio	n available										
10.0	-												
12.6.			upting propert				• • •						
			/mixture does i REACH Article 5		•								
			J) 2018/605 at l										



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12.7.	Other adverse effects	
	No information available	
SECTIO	N 13. Disposal considerations	
13.1	Waste treatment methods	
13.1.1.	Product/Packaging disposal:	
	-	ed of according to the national and local rules and regulations. Do not Submit for disposal to the legal person authorized by the Ministry of tection.
13.1.2.	Waste codes/waste designatio	
	15 01 10*: packaging that cont substances	ains residual hazardous substances or is contaminated with hazardous
13.1.3.	Waste treatment – relevant info	ormation:
	No information available	
13.1.4.	Sewage disposal – relevant info	ormation:
	Waste must not be disposed o	f into the sewage system.
13.1.5.	Other disposal recommendation	ons:
	authorized by the ministry in cl	's remains into the sewage system. Submit the remains to the collectors harge. Do not dispose of the packaging into the sewage system. Submit s authorized by the ministry in charge.
13.1.6.	Relevant Community provision	s:
	Directive 2009/98/EC on waste	and repealing certain directives.
SECTIO	N 14 TRANSPORT INFORMATIO	DN
	Transporting/shipment by road ((ADR)
UN nun	nber:	Not subject to transport regulations
UN pro	per shipping name:	-
Transpo	ort hazard class(es):	-
Packing	group:	-
Environ	mentally hazardous:	-
Special	precautions for user:	-



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Transporti	ng/shipment by rail (RI	D)							
UN number:		Not subject to transport regu	lations						
UN proper shipping	g name:	-							
Transport hazard cl	ass(es):	-							
Packing group:		-							
Environmentally ha	zardous:	-							
Special precautions	for user:	-							
Inland wat	erway transport (ADN)								
UN number:		Not subject to transport regu	lations						
UN proper shipping	g name:	-							
Transport hazard cl	ass(es):	-							
Packing group:		-							
Environmentally ha	zardous:	-							
Special precautions	for user:	-							
Transporti	ng/shipment by sea (IN	1DG)							
UN number:		Not subject to transport regulations							
UN proper shipping	g name:	-							
Transport hazard cl	ass(es):	-							
Packing group:		-							
Environmentally ha	zardous:	-							
Special precautions	for user:	-							
Transport in bulk a of MARPOL 73/78 a	according to Annex II and the IBC code:	-							
Transporti	ng/shipment by air (ICA	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:		Ш							
Environmentally ha	zardous:	None							
Special precautions	for user:	No information							

Further information:

Formaldehyde solutions, nonflammable, containing less than 25% of formaldehyde do not adhere to the ADR regulations.

SECTIO	N 15. Regulatory information
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture



THR-OT-X**

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

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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 (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- 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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Trading name:Product code:THR-OT-X**			THROMBOGNOST SOLUTION			
		THR-OT-X**	Date of compilation: 03 April 2023 Version: 4			
16.2 Abbreviatio			ons 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.	6.5. Relevant H st		l statements (num	er 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.	6.6. Training advice:		dvice:	-		
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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