

LEUKOGNOST PLUS

The kit contains:

BioMount Aqua LeukoGnost Fixative LeukoGnost HEM



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

amended by Regulation (EU) No. 2020/878

Trade name:

BIOMOUNT AQUA

Product code: BMA-X** Date of compilation: 21 November 2022 Version: 5

1.1.	Product identifier	Product identifier				
	Trade name:	BIOMOU	BIOMOUNT AQUA			
	Chemical name:	-				
	Catalogue number:	BMA-X**	•			
1.2.	Relevant identified us	es of the su	bstance or mixt	cure and uses advised against		
	Uses:		Water-based cover slips.	medium for covering microscope slides and mounting		
	Uses advised against:		Only the ider	Only the identified uses are advised.		
	Reason why uses advi	sed	device, regist	is intended for use only as an <i>in vitro</i> diagnostic medical tered at the Agency for Medicinal Products and Medical there is no reason to use it for other purposes.		
1.3.	Details of the supplier of the safety data sheet					
	Supplier:		BioGnost Ltd.			
	Address:		Medjugorska 59, Zagreb			
	Telephone number:		+385 1 2409997			
	Telefax:		+385 1 2404039			
	e-mail of competent person:		msds@biognost.hr			
	National contact:		-			
1.4.	Emergency telephone	numbers				
	National Protection and Rescue Di		Directorate:	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 Regula	ation (EC) No 127	272/2008 (CLP)			
	Hazard class and categor	y code:	Hazard statement*:			
	Not identified as hazardous subst	ance.	-			
2.1.2.	Additional information					
	-					
* For fu	ıll text of Hazard- and EU Hazard-st	atements: see SI	SECTION 16			
2.2.	Label elements					
	Product identification:	BIOMOUNT AQ	QUA			
	Identification number:	-				
	Authorisation number:	_				



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	Hazard pictograms:	-
	Signal word:	-
	Hazard statement:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	The product has no other know	vn specific hazards for human or environment.
	Results of PBT and vPvB assess PBT or vPvB substances.	ment: Based on available data, the product does not contain any
	Endocrine disrupting property:	Based on available data, does not contain endocrine disruptors.

SECTION 3. Cor	SECTION 3. Composition/information on ingredients						
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)			
-	-	-	Contains no hazardous substances	-			

SECTI	ECTION 4. First aid measures				
4.1.	Description of first aid meas	ures			
	General notes:	Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident. Immediately remove any clothing soiled by the product.			
	Following inhalation:	Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness place patient stably in side position for transportation.			
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap and rinse thoroughly. If symptoms persist, consult a doctor.			
	Following eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.			
	Following ingestion:	DO NOT induce vomiting. If symptoms persist, consult a doctor.			
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.			
4.2.	Most important symptoms a	and effects, both acute and delayed			
	Following inhalation:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.			



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	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.	
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.	
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.	
4.3.	Indication of any immediate medical attention and special treatment needed		
	No further relevant information available.		

SECTIO	SECTION 5. Firefighting measures				
5.1.	Extinguishing media				
	Suitable extinguishing media:	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.			
	Unsuitable extinguishing media:	water with full jet			
5.2.	Special hazards arising from the subs	tance or mixture			
	Hazardous by products of fire:	Formation of toxic gases is possible during heating or in case of fire.			
5.3.	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.				
5.4.	Additional information				
	Collect contaminated firefighting water separately.				
	Do not contaminate the environment	with extinguishing media.			

SECTIO	TION 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). Keep unprotected persons away.			
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.			
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:	For emergency responders:			
	Use protective equipment; in case (see Section 8).	of inadequate ventilation use adequate airways protective equipment			
6.2.	Environmental precautions:				



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	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.		
6.3.	Methods and materials fo	or containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.	
6.3.2.	Cleaning up:	Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.	
6.3.3.	Other information:	Do not use tools that may cause sparks.	
6.4.	Reference to other sections		
	See Section 7 for information on safe handling.		
	See Section 8 for information on personal protection equipment.		
	See Section 13 for disposal information.		

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 heat and ignition. Carry out measures for preventing static electricity.	
	Measures to prevent aerosol and dust generation:		Secure proper ventilation.	
	Measures to protect the environment:	Prevent spilling into the sewage system waterways.		
	Other measures:	-		
7.1.2.	Advice on general occupational hygiene:			
	Do not eat, drink or smoke in the workspace. Thor	oughly wa	ash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompa	atibilities		
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from source of heat, sunlight, and other incompatible substances.		
	Packaging materials:	Manufacturer's original packaging.		
	Requirements for storage rooms and vessels:	Keep aw tightly c	vay from food and drink. Keep the containers closed.	



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	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-
SECTIO	ON 8. Exposure controls/personal protection	
8.1	Control parameters	

SECTION 8. I	Exposur	e contr	ols/persona	l protec	tion			
8.1. Con	trol para	meters						
Substance		CAS No			Occupational exposure limit values/short term values		Biological limit values	
					ppm	mg/m³		-
-			-		-	-	-	
Substance:	-							
EC No:	-		CAS No:	_				
DNEL								
					Industrial			
Route of expo	osure:		te effect local		cute effect systemic	Chronic e		Chronic effect systemic
Oral		_		-	,	-		-
Inhalation		-		-		-		-
Dermal		-		-		-		-
Critical physic	cal parar	neters: s	solubility, fla	mmabilit	ty, corrosivity:	-		
					Consumer	i .		
Route of exposure:			te effect local		cute effect systemic	Chronic e local		Chronic effect systemic
Oral		-		-		-		-
Inhalation -		_		-		-		-
Dermal -		-		-		-		
PNEC								
Environmenta	al protec	tion tar	get		PNEC			



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

8.2.	Exposure controls		
8.2.1.	Appropriate engineering control	s	
	Substance/mixture related measures to prevent exposure during identified uses:	Use personal protective equipment. Do not eat, drink or smoke in the workspace.	
	Structural measures to prevent exposure:	No information available	
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.	
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.	
8.2.2.	Personal protection equipment:		
8.2.2.1.	Eye and face protection:	Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU)	
8.2.2.2.	Skin protection		
		Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.	
	Hand protection:	Full contact: Glove material: Viton Glove thickness: 0.7 mm Break through time: 480 min	
		Splash contact:	
		Glove material: Nitrile rubber	
		Glove thickness: 0.4 mm	
		Break through time: 35 min	



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	Other skin protection:	Complete suit protecting against chemicals, flame retardant antistatic protective clothing (EN 13688). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
8.2.2.3.	Respiratory protection:	Where risk assessment shows air-purifying respirators are appropriate use type ABEK (EN 14387) respirator cartridges as a backup to engine protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as CEN (EU).
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

.1.	Information on basic physical and chemic	al properties	
		Value	Method
	Physical state:	liquid	No information available
	Colour:	pale yellow	No information available
	Odour/odour threshold:	no odor/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:	6.85 – 7.2	No information available
	Kinematic viscosity:	700-1000 cSt	No information available
	Solubility:	No information available	No information available



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	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:	No relevant information available.					
10.2.	Chemical stability:	The product is chemically stable under recommended storage conditions.					
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. To	oxicological information	on										
11.1. Informa	ation on toxicological e	n on toxicological effects										
Acute t	oxicity:											
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results							
Oral:	No information available	-	LD ₅₀	No information available	-							
Dermal:	No information available	-	LD ₅₀	No information available	-							
Inhalation:	No information available	-	LC ₅₀	No information available	-							
Specific	c target organ toxicity -	single expos	ure (STOT-SE):									
	Specif	ic effects		Target organ	Note							
Oral:	No information av	ailable	No in	formation available	-							
Dermal:	No information av	ailable	No in	formation available	-							
Inhalation:	No information av	ailable	Respi	ratory system	-							



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Aspiration	on hazard:			-					
Irritation	and corro	osion							
;		•	osure me	Species	Evalu	ation	Metho	od	Note
Skin corrosion/irr	itation	-	_		-		-	No infor	mation available
Serious eye damage/irritatior	1	-	-		-		-	No infor	mation available
Sensitiza	ation								
Skin sensitization	: N	o informa	tion availabl	е					
Respiratory sensitization:	N	o informa	tion availab	e					
	i								
Sympton	ms related	to physic	al, chemical,	and toxico	logical p	ropertie	S		
Oral exposure:		_	r findings, c ntirely teste	•	ysical an	nd toxico	logical	properties of t	he substance
Dermal exposure		_	r findings, c ntirely teste		ysical an	nd toxico	logical	properties of t	he substance
Inhalation exposure:	:	_	r findings, c	•	ysical an	nd toxico	logical	properties of t	he substance
Eye exposure:		_	r findings, c ntirely teste	•	ysical an	nd toxico	logical	properties of t	he substance
Reneate	d dose to	vicity (sub	acute, subch	ronic chro	nic)				
Repeate	Do		Exposure time	Species		Method		Evaluation	Note
Subacute oral	No info		No information available	No informa availabl	ition	No informa available		No information available	-
Subacute dermal	No info available		No information available	No informa availabl	ition	No informa available		No information available	-
Subacute inhalation	No info available		No information available	No informa availabl	ition	No informa available		No information available	-
Subchronic oral	No info		No information available	No informa availabl	ition	No informa available		No information available	-



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Subchronic dermal	No information available	No information available	No information available	No information available	No information available	on	-
Subchronic inhalation	No information available No information available		No information available	No information available	No information available	on	-
Chronic oral	No information available	No information available	No information available	No information available	No informati available	on	-
Chronic dermal	No information available	No information available	No information available	No information available	No informati available	on	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information	on	-
Specific	target organ toxic	-	-				
			Specific effects		Target organ		Note
Subacute oral			lo information available		No information available No information available		
Subacute derma			lo information available			-	
Subacute inhalat			lo information available		No information available		
Subchronic oral		lo information available		No information available		-	
Subchronic derm		lo information available		No information available		-	
Subchronic inhal		No information		No information a		-	
Chronic oral		lo information available		No information available		-	
	Chronic dermal		lo information available		No information available		
Chronic dermal						-	
		No information No information		No information a		-	
Chronic dermal Chronic inhalatio		No information	available	No information a			
Chronic dermal Chronic inhalatio	on	No information	available	No information a			
Chronic dermal Chronic inhalatic CMR ef Carcino	en fects (carcinogenic	No information	available y, reproductive	No information a e toxicity) on available			
Chronic dermal Chronic inhalatic CMR ef Carcino	fects (carcinogenic genicity: nicity <i>in-vitro</i> :	No information	available sy, reproductive No information	No information a e toxicity) on available on available			
Chronic dermal Chronic inhalatic CMR ef Carcino Mutage Genoto	fects (carcinogenic genicity: nicity <i>in-vitro</i> :	No information	available ry, reproductive No information	No information a e toxicity) on available on available on available			
Chronic dermal Chronic inhalatio CMR ef Carcino Mutage Genoto Mutage	fects (carcinogenic genicity: enicity <i>in-vitro</i> : xicity:	No information	available Ty, reproductive No information No information No information	No information a e toxicity) on available on available on available on available			



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11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	Based on available data, does not contain endocrine disruptors.
11.2.2.	Other information:
	-

SECTION 12. Ecologi	SECTION 12. Ecological information											
12.1. Toxicity	12.1. Toxicity											
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note						
Fish	LC ₅₀	96 hours	-	No information available	-	-						
Crustacea:	EC ₅₀	48 hours	-	No information available	_	_						
Algae/aquatic plants:	IC ₅₀	72 hours	-	No information available	_	-						
Other organisms:	-	-	-	-	-	-						
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note						
Fish	LC ₅₀	96 hours	-	No information available	_	-						
Crustacea:	EC ₅₀	48 hours	-	No information available	-	-						
Algae/aquatic plants:	IC ₅₀	72 hours	_	No information available	_	_						
Other organisms:	_	-	-	-	-	-						

12.2. Persistence and degradability Abiotic degradation Degradation half-lives Method Evaluation Note Marine No information available No information available No information available water Fresh water No information available Air -No information available No information available No information available Soil



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Biodegr				****			
% Degradation	Time (day			1ethod	Evaluation	N	ote
_	No info	mation	No inforn available	nation	No information available	-	
12.3. Bioaccu	mulative potenti	al					
Octanol	-water partition	coefficier	nt (log Kow	v)			
Value (Concentration	рН	°C	Method	Evaluatio	n	Note
No ava	information ailable	-		No information available	No information	on -	
:	entration Factor						
Value	Spec	ies	Method		Evaluation	<u> </u>	lote
-	-		No inf availat	ormation ole	-	-	
Chuaria							
Chronic	ecotoxicity		Evpocuro				
Value	Do	se	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity o	on fish LC ₅₀		o formation ailable	No information available	No information available	No information available	-
Chronic toxicity c crustacea (Daphr	; F (-0	1	o formation ailable	No information available	No information available	No information available	-
12.4. Mobility	in soil						
	or predicted dist	ribution i	n environn	nental compartr	nents:		
	mation available						
1.10							



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		Value	°C	Concentration	Method		Note
	No avai	information lable	No information available	No information available	No information a	available	-
	Ads	orption / desorptior	1				
Transpo	ort	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	١	lote
Soil-Wa	ater	No information	n No informatio available	n No information available	No information available	-	
Water-A	Air	No informatio available	n No informatio available	n No information available	No information available	-	
Soil-Air	•	No informatio available	n No informatio available	n No information available	No information available	-	
12.6.	Base	ocrine disrupting pr	the product does no	t contain any PBT or v	PvB substances.		
12.6.	Base	ed on available data, ocrine disrupting pr	the product does no	,	PvB substances.		
	End Base	ed on available data, ocrine disrupting pr	the product does no	,	PvB substances.		
	Endo Base	ed on available data, ocrine disrupting pr ed on available data,	the product does not operties	,	PvB substances.		
12.7.	Endo Base Otho	ed on available data, ocrine disrupting pro ed on available data, er adverse effects information available	the product does not operties does not contain ende	,	PvB substances.		
12.7. SECTIO	Base End Base Othe No i	ed on available data, ocrine disrupting produced on available data, er adverse effects information available. Disposal consider	the product does not operties does not contain ender	,	PvB substances.		
12.7. SECTIO	Base End Base Othe No i	ed on available data, ocrine disrupting pro ed on available data, er adverse effects information available	the product does not operties does not contain ender	,	PvB substances.		
12.7. SECTIO 13.1.	Endo Base Otho No i	ed on available data, ocrine disrupting produced on available data, er adverse effects information available. Disposal consider	the product does not operties does not contain ende	,	PvB substances.		
12.7. SECTIO 13.1.	Endo Base Otho No i	ocrine disrupting proceed on available data, er adverse effects information available. Disposal consider daste processing meters of the processing meters of the processing disposal conduct/Packaging disposal c	the product does not operties does not contain end e ations chods	,		and Natur	re
12.7. SECTIO 13.1.	Endo Base Otho No i	ocrine disrupting product/Packaging disposal to dispos	the product does not operties does not contain end e ations chods	docrine disruptors.		and Natur	re
12.7. SECTIO 13.1.	Base Othe No i Pr Su Pr	ocrine disrupting product/Packaging disposal to otection.	the product does not operties does not contain end e ations chods sposal: the legal person aut	docrine disruptors. horized by the Ministr		and Natur	re
12.6. 12.7. SECTIO 13.1. 13.1.2.	Endo Base Otho No i	ocrine disrupting product/Packaging disposal to otection.	the product does not operties does not contain ended e ations chods sposal: the legal person aut esignations according	docrine disruptors. horized by the Ministr		and Natur	re



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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:					
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: Disposal must be made according to official regulations. SECTION 14. Transport information Transporting/shipment by road (ADR) UN number: Not subject to transport regulations UN proper shipping name: - Transport hazard class(es): - Packing group: - ITransporting/shipment by rail (RID) UN number: Not subject to transport regulations UN proper shipping name: - Transport ny shipping name: - Transport hazard class(es): - Packing group: - Environmental hazards: - Special precautions for user: - Transport hazard class(es): - Packing group: - Environmental hazards: - Special precautions for user: - Transporting/shipment by inland waterways (ADN) UN number: Not subject to transport regulations UN proper shipping name: - Transporting/shipment by inland waterways (ADN) UN number: Not subject to transport regulations UN proper shipping name: - Transporting/shipment by inland waterways (ADN) UN number: Not subject to transport regulations UN proper shipping name: - Transporting/shipment by inland waterways (ADN) UN proper shipping name: - Transport hazard class(es): - Packing group: - Environmental hazards: - Fransporting/shipment by sea (IMDG)	13.1.4.	Sewage disposal – relevant information:			
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: Disposal must be made according to official regulations. SECTION 14. Transport information Transporting/shipment by road (ADR) UN number: Not subject to transport regulations UN proper shipping name:		Waste must not be disposed o	of into the sewage system.		
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Environmental hazards: - Special precautions for user: - Transporting/shipment by sea (IMDG)	Transport hazard class(es):		-		
Special precautions for user: - Transporting/shipment by sea (IMDG)	Packing group:		-		
Transporting/shipment by sea (IMDG)	Environm	ental hazards:	-		
	Special p	recautions for user:	-		
UN number: Not subject to transport regulations	7	Fransporting/shipment by sea (I	MDG)		
	UN numb	per:	Not subject to transport regulations		



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		ВІОМО	UNT AQUA		
Product code:	BMA-X**	Date of compilation:	21 November 2022	Version:	5
1111					
UN proper shipping		-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmental haza	rds:	-			
Special precautions	for user:	-			
Transport in b accordance with A 73/78 and IBC Code		in POL -			
Transporti	ng/shipment by a	ir (ICAO-TI/IATA-DGR)			
UN number:		Not subject to transpo	rt regulations		
UN proper shipping	ı name:	-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmental haza	rds:	-			
Special precautions	for user:	-			

SECTIO	ON 15. Regulatory infor	mation
15.1.	Safety, health and envi	ronmental regulations/legislation specific for the substance or mixture
	EU regulations	
	Authorisation and/or re	estrictions on use
	Authorisations:	-
	Restrictions:	-



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Trade name:		ВІОМО	UNT AQUA		
Product code:	BMA-X**	Date of compilation:	21 November 2022	Version:	5

	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; COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to
		Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 1999, guideline)	/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment	
	None	

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



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Trade name:		віомо	UNT AQUA		
Product code:	BMA-X**	Date of compilation:	21 November 2022	Version:	5

Key literature references and source of data:	-	
Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
cation	Classification procedure	
	-	
Relevant H statements (num	ber and full text)	
H: -	-	
Training advice:	-	
Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.	
	and source of data: Classification and procedure 1272/2008 (CLP) cation Relevant H statements (num H: - Training advice:	

ANNEY: Evacuire economic regulting to Chemical sofety assessment	
ANNEX: Exposure scenario resulting to Chemical safety assessment	
-	



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Trading name:		LEUKOGNOST	FIXATIVE		
Product code:	LKF-X*	Date of compilation:	14 September 2022	Version:	2

1.1	Product identifier				
	Trading name:	LEUKOGNO	LEUKOGNOST FIXATIVE		
	Chemical name:	-			
	Catalogue number:	LKF-X*			
1.2	Relevant identified us	ses of the subs	tance or n	nixture and uses advised against	
	Uses:		For use	in cytochemical diagnostics of leukemia.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses adv	ised against:	medical	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:		BioGnost Ltd. Medjugorska 59, Zagreb		
	Address:				
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2	2404039	
	e-mail of competent	person:	msds@b	piognost.hr	
	National contact:		-		
	National Contact.				
1.4	Emergency telephone	e number			
1.4			ectorate:	112	
1.4	Emergency telephone		ectorate:	112 +385 1 2348 342	

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 statements*:			



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

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Trading name:	LEUKOGNOST FIXATIVE				
Product code:	LKF-X*	Date of compilation:	14 September 2022	Version:	2

Product code:	LKF-X*	Date of c	ompilation:	14 September 2022	Version:	2
Flam. Lic	լ. 2		H225			
Acute To	ox. 4		H302			
Acute To	ox. 4		H312			
Skin Irrit	. 2		H315			
Skin Sen			H317			
Eye Irr. 2			H319			
Acute To			H332			
STOT SE	3		H336			
Muta. 2			H341			
Carc. 1B			H350			
			EUH066			
2.1.2. Addition	al information					
-						
*For full text of H	azard- and EU Haz	ard-statements: see S	SECTION 16			
2.2 Label ele	ements					
Product	identification:	LEUKOGNOST	FIXATIVE			
Identifica	ation number:	-				
Authoriz	ation number:	-				
Hazard p	oictograms:	GHS02				

GHS08

Danger

Signal word:



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Trading name:	LEUKOGNOST FIXATIVE				
Product code:	LKF-X*	Date of compilation:	14 September 2022	Version:	2

P280 Wear protective gloves/protective clothing/eye/protection/factor protection. P301+P330+P331 IF SWALLOWED: rinse mouth. DO NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/attention. EUH066 Repeated exposure may cause skin dryness or cracking.
 P280 Wear protective gloves/protective clothing/eye/protection/fac protection. P301+P330+P331 IF SWALLOWED: rinse mouth. DO NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P210 Keep away from heat/sparks/open flames/hot surfaces. Do no smoke.
 H225 Highly flammable liquid and vapor. H302 + H312 + H332 Harmful if swallowed, in contact with skin or ininhaled. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H341 Suspected of causing genetic defects. H350 May cause cancer.

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)	
67-64-1/ 200-662-2/ 606-001-00-8	-	≥ 70 % - < 90 %	acetone	Flam. Liq. 2; H225 Eye Irr. 2; H319 STOT SE 3; H336 EUH066	
50-00-0/ 200-001-8/ 605-001-00-5	01-2119488953-20- XXXX	7 - 10 %	formaldehyde, 37%	Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr. 1B; H314 Skin. Sens. 1, H317 Muta. 2; H341 Carc. 1B; H350	



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Trading name:		LEUKOGNOST	FIXATIVE		
Product code:	LKF-X*	Date of compilation:	14 September 2022	Version:	2

4.1	Description of first aid measures				
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.			
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.			
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.			
	Following ingestion:	Do not induce vomiting. Do not insert any object into the unconscious person's mouth. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.			
	Self-protection of the first aider:	-			
4.2	Most important symptoms and effects, both acute and delayed				
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.			
	Following skin contact:	Defatting, dry skin.			
	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.			

SECTION	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO2 Large fire - water spray or alcohol resistant foam			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the s	ubstance or mixture			
	Hazardous combustion products:	Carbon monoxide (CO)			
5.3	Advice for firefighters				



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Trading name:	LEUKOGNOST FIXATIVE				
Product code:	LKF-X*	Date of compilation:	14 September 2022	Version:	2

	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.	

SECTIO	ON 6. Accidental release measu	ures		
6.1	Personal precautions, protective equipment and emergency procedures			
6.1.1.	For non-emergency personnel			
	Protective equipment:	Use personal protective equipment (see Section 8).		
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.		
	Emergency procedures:	Mark the area using proper signs.		
6.1.2.	For emergency responders:			
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).			
6.2	Environmental precautions:			
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.			
6.3	Methods and material for 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 of See Section 8 for information of See Section 13 for disposal info	on personal protection equipment.		

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



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Trading name:		LEUKOGNOST	FIXATIVE		
Product code:	LKF-X*	Date of compilation:	14 September 2022	Version:	2

	Measures to prevent fire:		Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.		
	Measures to prevent aerosol and dust generation	Secure proper ventilation.			
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:		-		
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. Th	noroughly was	sh hands after work and before eating.		
7.2	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:	well ventil	ghtly closed and upright set containers in a ated storage rooms at temperatures ranging 25 °C. Protect from heat and direct sunlight.		
	Packaging materials:	Manufactu	cturer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away	yay from food and drink. Keep the containers losed.		
	Advices for storage equipment:	must be re	ge must be made of hard material; floors esistant to chemicals. There must be no drain ly leads into sewage system. Secure proper n.		
	Further information on storage conditions:	and do no	ace the unused material in the storage room of 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 con	rols/personal prot	tection		
8.1 Control parameter	S			
Substance	CAS No	· ·	exposure limit term values	Biological limit values
		ppm	mg/m³	
Acetone	67-64-1	500	1210	No information available
Formaldehyde	50-00-0	2	2.5	No information available
Substance name: -				
EC No: -	CAS No:	-		



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DNEL					
		Indi	ıstrial		
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic	
Oral	-	-	-	-	
Inhalation	1 mg/m3 (formaldehyde)	-	0.5 mg/m3 (formaldehyde)	1210 mg/m³ (acetone) 9 mg/m3 (formaldehyde)	
Dermal	-	-	0.037 mg/cm2 (formaldehyde)	186 mg/kg (acetone) 240 mg/kg (formaldehyde)	
Critical physical p	parameters: solubility,	flammability, corre	osivity: -		
		Con	sumer		
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic	
Oral	-	-	-	4.1 mg/kg (formaldehyde)	
Inhalation	-	-	200 mg/m3 (acetone) 0.1 mg/m3 (formaldehyde)	3.2 mg/m3 (formaldehyde)	
Dermal	-	-	62 mg/kg (acetone) 0.012 mg/cm2 (formaldehyde)	120 mg/kg (formaldehyde)	
PNEC			(
Environmental pr	otection target	1	PNEC		
Fresh water			10.6 mg/l (acetone) 0.47 mg/l (formaldehyde)		
Freshwater sedin	nents		30.4 mg/kg (acetone) 2.44 mg/kg (formaldehyde)	
Marine water			1.06 mg/l (acetone) 0.47 mg/l (formaldehyde)		
Marine sediment	S		3.04 mg/kg (acetone) 2.44 mg/kg (formaldehyde)		
Food chain			No information available		
Microorganisms	in sewage treatment		100 mg/l (acetone) 0.19 mg/l (formaldehyde)		
Soil (agricultural)			29.5 mg/kg (acetone) 0.21 mg/kg (formaldehyde)		
Air			No information available		
8.2 Expo	osure controls				



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8.2.1.	Appropriate engineering controls				
	Substance/mixture related measures to prevent exposure during identified uses: Structural measures to prevent exposure:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.		
			In accordance with Section 7.		
	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.		
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	levels	glasses that stick to face (EN 166) or visor in case of lower of concentration in air; protective gas mask that covers the face in case of higher levels of concentration in air.		
8.2.2.2.	Skin protection				
	Hand protection:	Regul 374.F	rotective gloves have to satisfy the specification of lation (EU) 2016/425 and the related standard EN ull contact: Glove material: butyl rubberGlove thickness: ≥ 0.50 mm Time until perforation: > 480 plash contact: Glove material: nitrile rubber Glove thickness: 0.4 mm Break through time: 35 min		
	Other skin protection:	suitabl cover t of imp	every day work use antistatic clothing (EN 13688) and e footwear, such as rubber boots (EN 20345) or shoes that the entire foot. In case of spilling hazard, use clothing made ermeable material suitable for protection from liquid cals (Viton, PVC, himex) and footwear made from the same al.		
8.2.2.3.	Respiratory protection:	ofinad	concentration level exceeds the GVI values (or because equate ventilation), use a filter for organic vapors, type iling point >65°C) according to EN 14387.		
8.2.2.4.	Thermal hazards:	:	ormation available		
8.2.3.	Environmental exposure controls				
	Substance/mixture related measures to prevent exposure:	See Se	ction 6		



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Structural measures to prevent exposure:	Use modern equipment.
Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
Technical measures to prevent exposure:	See Section 6

	Information on basic physical and o	chemical properties	
		Value	Method
	Physical state:	liquid	Visual inspection
	Color:	colourless	Visual inspection
	Odour/odour threshold:	acetone 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:	5.25 – 5.35	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
	Physical state:	No information available	No information available
.2	Other information		

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



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10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3	Possibility of hazardous reactions:	No dangerous reactions known.
10.4	Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	Carbon monoxide.

SECTION 11. T	oxicological infor	mation					
11.1 Inform	ation on toxicolog	ical effects					
Acute	toxicity:						
Route of exposure:	Method	Species	Do	ose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure t	ime Results	
Oral:	-	rat		LD ₅₀	_	>2,000 mg/kg (acetone)	
Dermal:	-	rat		LD ₅₀	-	>2,000 mg/kg (acetone)	
Inhalation:	-	rat		LD ₅₀	4 h	20 mg/l (acetone)	
Specifi	ic target organ toxi	city – sinale ex	xnosure (S	STOT SE)·			
эрссііі		ecific effects		Target or	gan	Note	
Oral:	No informati			No information available		-	
Dermal:	No informati			No information available		_	
Inhalation:	No informati			No information av	may cause drowsiness or dizziness		
Aspira	tion hazard:		No infor	mation available.			
Irritatio	on and corrosion						
	Expos	ure time	Spec	ies Evaluatio	n Method	Note	
Skin corrosion/irritat	tion:		-	-	-	-	
Serious eye damage/irritation			_	-	-	causes serious eye irritation	
Sensiti	zation						
Skin sensitizatio	on: -						
Respiratory sen	sitization: -						



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Oral exposure:	No informat	ion available.				
Dermal exposure: No information		ion available.				
Inhalation expos	ure: No informat	ion available.				
Eye exposure:	No informat	ion available.				
Repeate	ed dose toxicity (sul	pacute, subchro	onic, chronic)	·	:	
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	Chronic oral 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	-



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Subacu	te oral	No information available	V	lo information available	-		
Subacu	te dermal	No information available	N	lo information available	-		
Subacu	te inhalation	No information available	N	lo information available	-		
Subchro	onic oral	No information available	N	lo information available	-		
Subchro	onic dermal	No information available	N	lo information available	-		
Subchro	onic inhalation	No information available	V	lo information available	-		
Chronic	oral	No information available	V	lo information available	-		
Chronic	dermal	No information available	V	lo information available	-		
Chronic	inhalation	No information available	١	lo information available	-		
	CMR effects (c	arcinogenicity; mutagenicity; re	eproductive tox	cicity)			
	Carcinogenicity	y:	Based on ava	ilable data, the classificati	on criteria are not		
	Mutagenicity <i>ii</i>	n vitro:	Based on available data, the classification criteria are not met.				
	Genotoxicity:		Based on available data, the classification criteria are not met.				
	Mutagenicity <i>ii</i>	n vivo:	Based on available data, the classification criteria are not met.				
	Germ cell muta	agenicity:	Based on available data, the classification criteria are not met.				
	Reproductive t	oxicity:	Based on available data, the classification criteria are not met.				
	Summary of properties:	evaluation of the CMR	Based on ava met.	ilable data, the classificati	on criteria are not		
11.2.		other hazards:					
11.2.1.		upting properties:					
	No known end that affect hun	docrine disrupting properties nan health.					
11.2.2.	Other informat	tion:					
	-						

SECTION 12. Ecological information								
12.1 Toxicity								
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		



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Fish		LC ₅₀	96 hours	fish	No information available	>1,000 (acetor	_	-	
Crustacea:		EC ₅₀	48 hours	Daphnia magna	No information available	>1,000 (aceto	_	-	
Algae/aquatic plants		IC ₅₀	8 days	algae	No information available	>1,000 (aceto	_	-	
Other organism	าร	-	72 hours	-	-	-		-	
Chronic (long-t	erm)	Dose	Exposure time	Species	Method	Evalu	ation	Note	
Fish		LC ₅₀	96 hours	No information available	No information available	No inform availab		-	
Crustacea:		EC ₅₀	48 hours	No information available	No information available	No inform availab		-	
Algae/aquatic p	olants	IC ₅₀	72 hours	No information available	No information available	No inform availab		-	
Other organism	าร	-	_	-	-	-		-	
12.2 Persist	ence a	nd degradab	ility						
Abioti	c degra	dation			·				
	De	gradation ha	lf-lives	Method	Evaluatio	on		Note	
Marine water	No ir	nformation av	vailable	No information available	No information - available		-		
Frosh water	No ir	oformation as	vailablo	No information	No informatio	No information			

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

Biodegradation

bloacgiada	CIOTI			
% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	1



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						:				-				:
12.3	Bioacc	umu	lative po	otential										
	Octano	ol-wa	ater part	ition coe	efficient	(log Kow	/)							
Valu	e	Con	centrati	on	рН	°C	М	ethod	1	Evalu	ation		Note	
_			formatio	n _		_		ormatio		No inform	nation	_		
	а	vaila	ble				availab	le		available				
									8 8 8 9 9 9 9 9 9					
	1	ncent	ration fa	actor (BC	.F)									
	/alue			Species			Method			Evaluati			Note	
No into	rmation le		No availab		mation	No inte	ormatio	on		informati ilable	ion		No information available	
avanao			avanao			avanas			uve			u.u.i.		
	Chroni	ic ec	otoxicity	,										
	Value	2		Dose		oosure	Sp	ecies	١	Лethod	Eva	luation	Not	te
						ime								
Chronic	toxicity	on f	fish	LC ₅₀	No infor	mation	No infor	mation	No info	ormation	No inform	nation	_	
Cilionic	Coxicity	0111	1311	LC30	avail		availa			ilable	availa			
Chronic	toxicity	, on			No		No		No		No			
	ea (<i>Dapl</i>			EC ₅₀	1	mation		mation		ormation	inform		-	
					avaii	able	availa	abie	ava	ilable	availa	oie		
12.4	Mahili	tv :-	soil											
12.4	Mobili	-		مانمهام	ıtian in		nontal i			.				
		······································	ation ava		ation in	environn	nemar	Lompan	unen	ts.				
	Surfac			illable										
		lue	ision.	°C		`ancontr	ation		N / A	athad			Noto	
	No Va	iue	No			Concentra	auun		IVI	ethod			Note	
	inform	nation		rmation		informa	ation	No int		ation	_			
	availab	ole	ava	ilable	av	ailable		availa	bie					



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	sorption / desorption				
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-
	sults of PBT and vPvB assessed on available data, the p		contain any PBT or v	PvB substances.	
12.6. End	docrine disrupting propert	ies			
No	known endocrine disrupti	ng properties that	affect the environn	nent.	
12.7	h a u a di vaua a affa ata				
	her adverse effects o information available				
INO	illomation available				
SECTION 1	3. Disposal consideration	S			
	Vaste treatment methods				
13.1.1. P	Product/Packaging disposa	l:			
	Submit for disposal to the l Protection.	egal person autho	rized by the Ministr	y of Environmental a	and Nature
13.1.2. V	Waste codes/waste designa	ations according to) Law:		
N	No information available				
		information			
	Waste treatment – relevant	inionnation.			
	Waste treatment – relevant No information available	imormation.			
N					
13.1.4. S	No information available	information:	ge system.		



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	authorized by the ministr	oduct's remains into the sewage system. Submit the remains to the collectors y in charge. Do not dispose of the packaging into the sewage system. Submit ectors authorized by the ministry in charge. Do not dispose of in places where
13.1.6.	Relevant Community pro	visions:
	-	
SECTION	14 TRANSPORT INFORM	IATION
-	Transporting/shipment by	road (ADR)
UN numb	per:	1090
UN prope	er shipping name:	Acetone
Transport	hazard class(es):	3
Packing o	group:	ll .
	entally hazardous:	-
Special p	recautions for user:	-
-	Transporting/shipment by	rail (RID)
UN numb	er:	1090
UN prope	er shipping name:	Acetone
Transport	hazard class(es):	3
Packing o	group:	II .
Environm	entally hazardous:	-
Special p	recautions for user:	-
	nland waterway transport	(ADN)
UN numb	per:	1090
UN prope	er shipping name:	Acetone
Transport	hazard class(es):	3
Packing o	ıroup:	II .
Environm	entally hazardous:	-
Special p	recautions for user:	-
-	Transporting/shipment by	sea (IMDG)
UN numb	oer:	1090
UN prope	er shipping name:	Acetone
Transport	hazard class(es):	3
Packing g	ıroup:	II .
Environm	entally hazardous:	-
Special p	recautions for user:	-



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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:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	П
Environmentally hazardous:	-
Special precautions for user:	-
Further information: -	

5.1 Safety, health and envir	Safety, health and environmental regulations/legislation specific for the substance or mixture				
EU regulations					
Authorization and/or re	strictions 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);				



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

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



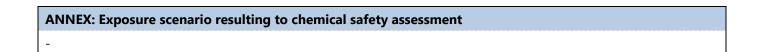
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	H:	225	Highly flammable liquid and vapor.
	301+311+331		Toxic if swallowed, in contact with skin and if inhaled.
		302	Harmful if swallowed.
		312	Harmful in contact with skin.
		314	Causes severe skin burns and eye damage.
		315	Causes skin irritation.
		317	May cause an allergic skin reaction.
	319		Causes serious eye irritation.
	332		Harmful if inhaled.
	336		May cause drowsiness or dizziness.
		341	Suspected of causing genetic defects.
		350	May cause cancer.
		EUH066	Repeated exposure may cause skin dryness or cracking.
16.6.	Trai	ning advice:	-
16.7.	Further information:		-





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Trading name:	LEUKOGNOST HEM				
Product code:	LKH-OT-X**	Revision date:	03 April 2023	Version:	2

SECTI	ON 1 IDENTIFICATION	OF THE SUBS	TANCE/MI)	KTURE AND OF THE COMPANY/UNDERTAKING	
1.1.	Product identifier				
	Trading name:	LEUKOGNO	ST HEM		
	Chemical name:	-			
	Catalogue number:	LKH-OT-X*	*		
1.2.	Relevant identified use	es of the subs	tance or mix	ture and uses advised against	
	Uses:		Hematoxyl	lin reagent for use with LeukoGnost kits.	
	Uses advised against:		Only the ic	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	Details of the supplier of the safety data sheet			
	Supplier:	Bi	BioGnost Ltd.		
	Address:	М	Medjugorska 59, Zagreb		
	Telephone number:	+.	+385 1 2409997		
	Fax no.:	+.	+385 1 2404039		
	e-mail of competent p	erson: <u>m</u>	msds@biognost.hr		
	National contact:	National contact: -			
1.4.	Emergency telephone	number			
	National Protection ar	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2 HAZARDS INFORMATION				
2.1.	Classification of the substa	Classification of the substance or mixture			
2.1.1.	Classification (REGULATIO	N (EC) No. 1272/2008	(CLP)		
	Hazard class and c	ategory code:	Hazard statements*:		
	Acute Tox. 4 H302				
2.1.2.	Additional information				
	-				
*For fu	ıll text of Hazard- and EU Haz	zard-statements: see S	ection 16		
2.2.	Label elements				
	Product identification:	ct identification: LEUKOGNOST HEM			
	Identification number:	-			
***************************************	Authorization no.:	-			



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Trading name:	LEUKOGNOST HEM				
Product code:	LKH-OT-X**	Revision date:	03 April 2023	Version:	2

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

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

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



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Product code:	LKH-OT-X**	Revision date:	03 April 2023	Version:	2

	Following ingestion:		Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.	
	Self-protection of the first a	aider:	Treat symptomatically.	
4.2.	Most important symptoms	and eff	ects, both acute and delayed	
	Following inhalation:		lation of large amounts of vapors in inadequately ventilated perimeter cause coughing, sneezing, headache and nausea.	
	Following skin contact:	_	nt irritation. After short exposure, resorption effects are not likely. Long- n exposure may cause drying, cracking and tingling sensation of skin.	
	Following eye contact:		ct eye contact may cause slight to moderate irritation, lacrimation and ning sensation. If the symptoms persist, immediately call a physician.	
	Following ingestion:	burr abdo couç	Swallowing may cause irritation of mucosa, tingling sensation in the mour 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 immediat	e medio	cal attention and special treatment needed	
	-			

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

SECTIO	ON 6 ACCIDENTAL RELEASE MEASU	RES
6.1.	Personal precautions, protective equ	uipment and emergency procedures
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).



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

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



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

SECTION 8 EXPOSU	RE CON	TROLS/PER	SONAL	PROTECTION			
8.1. Control para	ameters						
Substance		CAS No		Occupational e		Biological limit values	
				ppm	mg/m³		
Ethylene glycol 107			-1	20/40	52/104	No infor	mation available
Substance name:							
EC No: -		CAS No:	-				
DNEL							
				Industrial			
Route of	A	Acute		Acute	Chron	ic	Chronic
exposure:	effe	ect local	effect systemic		effect local		effect systemic
Oral	-		-		-		-
Inhalation	-		-		35 mg/ kg (ethylene gly	col)	
Dermal	-		-		-		106 mg/kg (ethylene glycol)
Critical physical para	meters: s	olubility, fla	mmabili	ty, corrosivity:	-		
				Consumer			



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Product	Loue.	LKH-U1-X***		Revisio	m date.	03 April 2023	version. 2		
		1							
Route of		Acute		Acut		Chronic	Chronic		
exposure	:	effect local	6	effect sys	temic	effect local	effect systemic		
Oral		-	-			-	-		
Inhalation	ı	-	-			7 mg/kg (ethylene glycol)	-		
Dermal		-	-			-	53 mg/kg (ethylene glycol)		
PNEC									
Environme	ental protec	ction target			PNEC				
Fresh wate	er				10 mg/l ((ethylene glycol)			
Freshwate	r sediment	s			37 mg/kg	g (ethylene glycol)			
Marine wa	ater				1 mg/l (e	thylene glycol)			
Marine sediments					3.7 mg/k	g (ethylene glycol)			
Food chain					No inform	mation available			
Microorganisms in sewage treatment					199.5 mg/l (ethylene glycol)				
Soil (agricultural)				1.53 mg/kg (ethylene glycol)					
Air					No infor	mation available			
8.2.	Exposure	e controls							
8.2.1.	Enginee	ring measures							
	measure	ce/mixture related s to prevent expo dentified uses:			•	n well ventilated rooms ot eat, drink or smoke i	s. Use personal protective n the workspace.		
	Structura	al measures to pre e:	event	No information available					
	_	ational measures t exposure:	:O	Organization of work in order to reduce other worker's influence during work process.					
	Technica exposure	al measures to pre e:	vent		ure proper workspace ventilation in order to keep centration levels in air below permitted levels.				
8.2.2.	Personal	protection equip	ment						
8.2.2.1.	Eye and	face protection:		Safety g	glasses tha	t stick to face (prevent	ing splashing) (EN 166) or		
8.2.2.2.	Skin pro	tection							
	Uand or	otoction:	Protect	_	e gloves must be according to standard EN 374. Glove material: nitrile rubber				
	папи рг	otection:		Glove thickness: ≥0.11 mm Break through time: >480 min					
	Die				DIEAK UIIOUYII UIIIE. 2400 IIIIII				



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	Other skin protection:		Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).		
8.2.2.3.	Respiratory protection:	filter f	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 relate measures to prevent exp		See Section 6		
	Structural measures to pexposure:	revent	Use modern equipment.		
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.		
	Technical measures to prexposure:	event	See Section 6		

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



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	Particle characteristics:	No information available	No information available
9.2.	Other information		
	-		

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

SECTION 11 TOXIC	OLOGICAL INFORMA	ATION			
11.1. Information	n on hazard classes as	defined in Reg	gulation (EC) No 1272	2/2008	
Acute toxic	rity:				
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	anhydrous (ECHA)	rabbit	LD ₅₀	-	7.712 mg/kg (ethylene glycol)
Dermal exposure:	anhydrous (ECHA)	rat	LD ₅₀	-	>3.500mg/kg (ethylene glycol)
Inhalation exposure:	No information available	-	LC ₅₀	_	-
**					
Specific tar	get organ toxicity – si	ngle exposure	(STOT SE):		
	Specif	ic effects	Target	organ	Note
Oral exposure:	No information	available	No informatio	n available	-
Dermal exposure:	No information	available	No informatio	n available	-
Inhalation exposure	: No information	available	No informatio	n available	-
Respiratory	r irritation:	No info	ormation available		
Irritation a	nd corrosion				
	Exposure time	Species	s Evaluation	Method	Note



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Product code:	LKH-OT-X**	Re	vision date:	03 April 202	Wersion:	2		
	***	1			***			
Skin irritation:	-	rabb	it -	-	Slight irritation glycol)	on (ethylene		
Eye irritation:	24 h	rabb	it -	-	Slight irritation glycol)	on (ethylene		
Sensitiza	ation							
Dermal exposure	: No information	n available						
Inhalation exposure:	No information	n available						
Sympto	ms related to the p	hysical, chemic	al and toxicolog	gical characteristi	ics			
Oral exposure:	No informat	ion available						
Dermal exposure	: No informat	ion available						
Inhalation exposi	ure: No informat	ion available						
Eye exposure:	Causes serio	ous eye damage	9					
Repeate	d dose toxicity (sul	pacute, subchro	onic, chronic)					
	Dose	Exposure time	Species	Method	Evaluation	Note		
Subacute oral	No information available	No information available	No information available	No information available	No information available	-		
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-		
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	_		
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-		
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	_		
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-		
Chronic oral	No information available	No information available	No information available	No information available	No information available	-		



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Trading name:		LEUKOGNOST HEM								
Product code:	LKI	H-OT-X**	Re	vision date	e:	03 April 2023	3	Version:	2	
Chronic dermal	No availa	nformation ble	No information available	No information	on	No information available	No inta	formation ble	-	
Chronic inhalation		lo information information		No information available	on	No information available		formation ble	-	
Specific	target	organ tovicit	y – repeated e	vnosura (ST	-OT R	E)·				
Specific	target		pecific effects	xposure (5)	011	Target orga	ın	***************************************	Note	
Subacute oral	No information available				No i	nformation avail				
Subacute derma						nformation avail		-		
Subacute inhalat	ion	No informa	ntion available		No i	nformation avail	able	-		
Subchronic oral		No informa	ition available		No i	nformation avail	able	-		
Subchronic derm	nal	No informa	ntion available		No i	nformation avail	able	-		
Subchronic inhal	ation	No informa	ntion available		No i	nformation avail	able	-		
Chronic oral		No informa	ntion available		No information available -					
Chronic dermal		No informa	ntion available	on available No ir		lo information available		-	-	
Chronic inhalation	n	No informa	tion available		No i	nformation avail	able	-		
			y, mutagenicity							
Carcino						nimals did not in			effects.	
Mutage	·····	n-vitro:				d not indicate r	nutager	nic effects.		
Genoto: Mutage	·····			nation avail		d not indicate n	t.a.a.a.	is offerts		
		genicity:		nation avail		a not indicate n	iutagen	ic effects.		
Reprodu						ctive organs w	as dete	ermined in	reproductive	
Summa	ry of ev	aluation of t	he CMR prope	rties: -						
11.2. Informa	tion on	other hazard	ds:							
11.2.1. Endocri	ne disru	upting prope	rties:							
	nown ies that	endocrine affect huma	disrupting n health.							
11.2.2. Other in	format	ion:								
-										



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12.1. Toxici	-									
Acute (short-te toxicity	erm)	Dose	Exposu time		Species	М	ethod	Eva	luation	Note
Fish		LC ₅₀	96 hour	`S	Fish		No rmation ailable		60 mg/l ne glycol)	-
Crustacea:		EC ₅₀	48 hour	S	water flea		No rmation ailable		00 mg/l ne glycol)	-
Algae/aquatic	plants	IC ₅₀	8 days		algae		No rmation ailable		3.000 mg/l ne glycol)	-
Microorganism	าร	LC ₅₀	72 hour	's	-	-			-	-
Chronic toxicit	у	Dose	Exposu time		Species	М	ethod	Eva	luation	Note
Fish		LC ₅₀	96 hours		No information available		rmation lable	No info availabl	rmation e	-
Crustacea:		EC ₅₀	48 hour	S	No information available		rmation lable No information			-
Algae/aquatic	plants	IC ₅₀	72 hours		No information available	No information available		No info availabl	rmation e	_
Other organisr	ns	-	-		-	-		-		-
		1	1						·	
12.2. Persis	tence a	nd degradal	oility							
Abiot	ic degra	dation								,
	Deg	radation hal	f-lives		Method			Evaluat	ion	Note
Marine water	No inf	ormation av	ailable	No	information availa	able	No info	mation a	vailable	-
Fresh water	No inf	ormation av	ailable	No	information availa	able	No infor	mation a	vailable	-
Air	No inf	ormation av	ailable	No	information availa	able	No infor	mation a	vailable	-
Soil	No inf	ormation av	ailable	No	information availa	able	No infor	mation a	vailable	-
Biode	gradati	on								
% Degradatio	_	Time (day	s)		Method	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Evaluat	ion	N	ote
No information	n No		mation	No in availa	nformation		o informa ailable	tion	No informa	tion



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Tradin	ng name:					LEUKOGI	INOST HEM				
Produ	ct code:	LKH-	OT-X**		Revi	sion date:	03 April 202	23	Version:	2	
12.3.	Bioaccum	nulative p	ootential								
	Partition	coefficie	nt: n-octa	nol/wate	er (log Ko	ow):					
Valu	ue Co	Concentration pH		°C Method		Evalu	ation	Note			
-	No avai	inforn lable	nation -		_	No informatio available	n No inform available	nation	-		
	Rioconco	ntration	factor (BC	·F)							
	Value	intration	Species	.1)	N	Method	Evaluati	on	<u> </u>	Note	
	No information No information available available		•	mation		ormation	No informati		No inform		
No info					available		available		available		
		availa	ble		avaiiab	ile					
		availa	ble		availab						
		availa	ble		avaliab	ile .					
	ble				avaliab	ile					
	Chronic e			Fyr							
	ble				oosure iime	Species	Method	Eva	luation	Note	
availab	Chronic e	cotoxici	ty Dose	No	posure ime	Species No	Method No		luation	Note	
availab	Chronic e	cotoxici	ty	No infor	posure cime	Species No information	Method No information		luation	Note -	
Chronic	Chronic e Value c toxicity or	ecotoxici n fish	ty Dose	No	posure cime	Species No	Method No	No info	luation ormation ble		
Chronic	Chronic e Value c toxicity or	n fish	ty Dose	No infor avail No infor	cosure time rmation able	Species No information available No information	Method No information available No information	No info	luation ormation ole		
Chronic	Chronic e Value c toxicity or	n fish	Dose	No infor avail No	cosure time rmation able	Species No information available No	Method No information available No	No info	luation ormation ole	-	
Chronic Chronic Chronic crustac	Chronic e Value c toxicity or c toxicity or cea (Daphni	n fish	Dose	No infor avail No infor	cosure time rmation able	Species No information available No information	Method No information available No information	No info	luation ormation ole	-	
Chronic	Chronic e Value c toxicity or c toxicity or cea (Daphnic	n fish n a)	ty Dose LC ₅₀ EC ₅₀	No infor avail No infor avail	cosure cime rmation able rmation able	Species No information available No information available	Method No information available No information available	No info	luation ormation ole	-	
Chronic	Chronic e Value c toxicity or c toxicity or cea (Daphnic	n fish n soil	ty Dose LC ₅₀ EC ₅₀	No infor avail No infor avail	cosure cime rmation able rmation able	Species No information available No information	Method No information available No information available	No info	luation ormation ole	-	
Chronic	Chronic e Value c toxicity or c toxicity or cea (Daphnic Mobility Known o	n fish n soil r predict	ty Dose LC ₅₀ EC ₅₀	No infor avail No infor avail	cosure cime rmation able rmation able	Species No information available No information available	Method No information available No information available	No info	luation ormation ole	-	
Chronic Chronic Chronic crustac	Chronic of Value c toxicity of the Company of the	n fish n soil r predict nation a	ty Dose LC ₅₀ EC ₅₀	No infor avail No infor avail	cosure cime rmation able rmation able	Species No information available No information available	Method No information available No information available	No info	luation ormation ole	-	
availab Chronio	Chronic e Value c toxicity or cea (Daphnic Mobility Known o No inforr Surface t	n fish n soil r predict nation are	ty Dose LC ₅₀ EC ₅₀ ed distribution vailable	No infor avail No infor avail ution in a	cosure cime cmation able cmation able	Species No information available No information available mental comparation	Method No information available No information available tments: Method formation	No info	luation ormation ole ormation ole	-	



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	Adsorption / desorption				
Transpo	ort .	A/D coefficient Henry's constant log Kow Evaporation ra		Method	Note
Soil-wat	ter No informa	tion No information available	No information available	No information available	-
Water-a	ir No informa available	tion No information available	No information available	No information available	-
Soil-air	No informa available	tion No information available	No information available	No information available	-
12.5.	Results of PBT and vPvB	accecement			
12.3.	Based on available data,		contain any PRT or v	/PvB substances	
	basea on available data,	and product does not	contain any i bi of v	vo sabstances.	
12.6.	Endocrine disrupting pro	perties			
	No known endocrine dis		t affect the environn	nent.	
		1 31 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2			
12.7.	Other adverse effects				
12.7.	Other adverse effects No adverse effects are e	xpected.			
12.7.		xpected.			
		·			
	No adverse effects are e	ERATIONS			
SECTIO	No adverse effects are e	ERATIONS			
SECTIO	No adverse effects are e	ERATIONS ods			
SECTION 13.1.	No adverse effects are e	erations ods posal:	orized by the Ministr	y of Environmental	and Nature
SECTION 13.1.	No adverse effects are e N 13 DISPOSAL CONSID Waste treatment meth Product/Packaging dis Submit for disposal to	erations ods posal: the legal person author	•	y of Environmental	and Nature
SECTIO I 13.1.	No adverse effects are e N 13 DISPOSAL CONSID Waste treatment meth Product/Packaging dis Submit for disposal to Protection.	erations ods posal: the legal person authorisignations according to	•	y of Environmental	and Nature
SECTIO I 13.1.	No adverse effects are e N 13 DISPOSAL CONSID Waste treatment meth Product/Packaging dis Submit for disposal to Protection. Waste codes/waste de	erations ods posal: the legal person authorisignations according to	•	y of Environmental	and Nature
SECTIO I 13.1.	No adverse effects are e N 13 DISPOSAL CONSID Waste treatment meth Product/Packaging dis Submit for disposal to Protection. Waste codes/waste de	ERATIONS ods posal: the legal person authorisignations according to	•	y of Environmental	and Nature
SECTIO I 13.1. 13.1.1.	No adverse effects are e N 13 DISPOSAL CONSID Waste treatment meth Product/Packaging dis Submit for disposal to Protection. Waste codes/waste de No information availab	erations ods posal: the legal person authorising to the legal	•	y of Environmental	and Nature
SECTIO I 13.1. 13.1.1.	No adverse effects are e N 13 DISPOSAL CONSID Waste treatment meth Product/Packaging dis Submit for disposal to Protection. Waste codes/waste de No information availab Waste treatment – rele	erations ods posal: the legal person authorising to the legal	•	y of Environmental	and Nature
SECTIO I 13.1. 13.1.1.	No adverse effects are e N 13 DISPOSAL CONSID Waste treatment meth Product/Packaging dis Submit for disposal to Protection. Waste codes/waste de No information availab Waste treatment – rele	erations ods posal: the legal person authorisignations according to the legal person authorise signations according to the legal person authorise signation according to the legal person according to the legal person authorise signation according to the legal person according to th	•	y of Environmental	and Nature



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



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

15.1.	Safety, health and enviror	N 15 REGULATORY INFORMATION Safety, health and environmental regulations/legislation specific for the substance or mixture		
	EU regulations			
	Authorization and/or rest	on 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		



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

amended by Regulation (EU) No. 2020/878

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Trading name:	LEUKOGNOST HEM				
Product code:	LKH-OT-X**	Revision date:	03 April 2023	Version:	2

15.2.	Chemical safety assessment
	None

SECTIO	ON 16 Other information				
16.1.	Indication of changes:	-			
16.2.	Abbreviations and acronym	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:	i –			
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
Classifi	cation	Classification procedure			
-		-			
16.5.	Relevant H statements (num	ber and full text)			
	H: 302	Harmful if swallowed.			
16.6.	Training advice:	-			
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX:

EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT