

LEUKOGNOST PLUS

The kit contains:

BioMount Aqua LeukoGnost Fixative LeukoGnost HEM



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

SECTI	ON 1: Identification of t	he substan	ce/mixture an	d of the company/undertaking		
1.1.	Product identifier					
	Trade name:	BIOMOUN	BIOMOUNT AQUA			
	Chemical name:	-				
	Catalogue number:	BMA-X**				
1.2.	Relevant identified use	s of the sub	ostance or mixtu	ure and uses advised against		
	Uses:		Water-based	medium for covering microscope slides and mounting cover slip		
	Uses advised against:		Only the iden	tified uses are advised.		
	-		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, r Devices and there is no reason to use it for other purposes.			
1.3.	Details of the supplier of the safety data sheet					
	Supplier:		BioGnost Ltd.			
	Address:		Medjugorska 59, Zagreb			
	Telephone number:	Telephone number:		+385 1 2409997		
	Telefax:		+385 1 2404039			
	e-mail of competent p	erson:	msds@biognost.hr			
	National contact:		-			
1.4.	Emergency telephone	Emergency telephone numbers				
	National Protection an	d Rescue D	irectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	ON 2. HAZARDS IDENTIFICAT	ION		
2.1.	Classification of the substance or mixture			
2.1.1.	Classification according to R	egulation (EC) No 1272/2008 (CLP)		
	Hazard class and cat	regory code: Hazard s		
	Not identified as hazardous	substance		
2.1.2.	Additional information			
	-			
* For fu	Ill text of Hazard- and EU Haza	rd-statements: see SECTION 16		
2.2.	Label elements			
	Product identification:	BIOMOUNT AQUA		
	Identification number:	-		
	Authorisation number:	-		
	Hazard pictograms:	-		
	Signal word:	-		



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Hazard	statement:	-					
Precaut	ionary statements:	-					
	metal hazard ntion (EU):	-					
2.3. Other h	ther hazards						
The pro	oduct has no other known specific hazards for human or environment.						
Results	of PBT and vPvB as	f PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB subs					
Endocr	ocrine 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	ON 4. First aid measures			
4.1.	Description of first aid measures			
	General notes:	Symptoms of poisoning may even occur after several hours; therefore medical observemove any clothing soiled by the product.		
	Following inhalation:	Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consu patient stably in side position for transportation.		
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap an		
	Following eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, con		
	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 descr		
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 sub		
	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the sub		
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the sub		
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the sub		
4.3.	Indication of any immediate	e medical attention and special treatment needed		
	No further relevant information available.			

SECTION 5. Firefighting measures



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5.1.	Extinguishing media			
	Suitable extinguishing media:	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol re		
	Unsuitable extinguishing media:	water with full jet		
5.2.	Special hazards arising from the substance 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	t with extinguishing media.		

SECTIO	ON 6. Accidental release m	easures			
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 personal		
	Accident prevention meth	ods:	Evacuate members of all non-essential personnel and those members v adequate ventilation and avoid contact with skin and eyes. Remove all sou		
	Emergency procedures:		Mark the area using proper signs.		
6.1.2.	For emergency responder	s:			
	Use protective equipment	; in case of i	nadequate ventilation use adequate airways protective equipment (see Sect		
6.2.	Environmental precaution	s:			
	Do not dispose of in sewa	ge, drainage	e system and waterways. In case of large spillage contact National Protectior		
6.3.	Methods and materials fo	r containme	nt and cleaning up		
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or	Sand or clay barriers.		
6.3.2.	Cleaning up:	imperme	Contain spillage, and then collect with an electrically protected vacuum cleaner or by impermeable containers. Store the substance in well ventilated storage rooms until c the Ministry of Environmental and Nature Protection. After disposal of the products,		
6.3.3.	Other information:	Do not use tools that may cause sparks.			
6.4.	Reference to other sections				
	See Section 7 for informat	tion on safe	handling.		
	See Section 8 for informat	tion on pers	onal protection equipment.		
	See Section 13 for disposal information.				

SECTI	ON 7. Handling and storage
7.1.	Precautions for safe handling



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7.1.1.	Protection measures				
	Measures to prevent fire:		Use in well ventilated storage rooms. Keep away from preventing static electricity.		
	Measures to prevent aerosol and dust generation	ו:	Secure proper ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterwa		
	Other measures:		-		
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.				
7.2.	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:		tightly closed and upright set containers in a well vent er incompatible substances.		
	Packaging materials:	Manufa	ufacturer's original packaging.		
	Requirements for storage rooms and vessels:	Кеер ам	p away from food and drink. Keep the containers tightly o		
	Advices for storage equipment:	The storage must be made of hard material; floors must l into sewage system. Secure proper ventilation.			
	Further information on storage conditions:	•	place the unused material in the storage room and do the incompatible materials (see Section 10).		
7.3.	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	-			

SECTION 8.	Exposur	e controls/person	al protec	tion								
8.1. Cor	ntrol para	arameters										
Sub	stance	CAS	No	Occupational ovalues/short	•							
				ppm	mg/m ³							
Substance:	-											
EC No:	-	CAS No:	-									
DNEL												
						Ir	ndustrial					
Route of exp	ocuro.	Acute effect	A	cute effect	Chronic e	effect						
Noule of exp	Josure.	local		systemic	local							
Oral		-	-		-		-					
Inhalation		-	-		-		-					
Dermal		-	-		-		-					



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Critical physical	parameters: solubility, fla	ammability, cor	rosivity:	-			
				(Consumer		
Douto of ovpos	Acute effect	Acute ef	ffect	Chronic effect			
Route of exposu	local	system	nic	local			
Oral	-	-		-	-		
Inhalation	-	-		-	-		
Dermal	-	-		-	-		
PNEC							
Environmental p	protection target		PNEC				
Fresh water			No inform	mation available			
Freshwater sedi	ments		No inform	mation available			
Marine water			No inform	mation available			
Marine sedimer	nts		No information available				
Food chain			No information available				
Microorganisms	s in sewage treatment		No information available				
Soil (agricultura	l)		No information available				
Air		No information available					
8.2. Exp	posure controls						
8.2.1. Ap	propriate engineering co	Introls					

Exposure controis								
Appropriate engineering controls								
Substance/mixture related measures to prevent exposure during identified uses:	Use personal protective equipment. Do not eat, drink or smoke in the work							
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 wo							
Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels i							
Personal protection equipment:								
Eye and face protection:	Face shield and safety glasses Use equipment for eye protection tested an EN 166(EU)							
Skin protection								
	 Appropriate engineering controls Substance/mixture related measures to prevent exposure during identified uses: Structural measures to prevent exposure: Organisational measures to prevent exposure: Technical measures to prevent exposure: Personal protection equipment: Eye and face protection: 							



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	Hand	protection:		with this product derived from it. Full contact: Glove Break Splash contact: Glove Glove	inspected prior to use. I ct. The selected protectiv e material: Viton e thickness: 0.7 mm < through time: 480 min e material: Nitrile rubber e thickness: 0.4 mm < through time: 35 min	ve gloves have t				
	Other	skin protection:			protecting against chemi d according to the conc					
8.2.2.3.	Respir	ratory protection:		engine protectio	ssment shows air-purifyi on, use a full-face suppli ndards such as CEN (EU	ied air respirator				
8.2.2.4.	Therm	nal hazards:	5		n available					
8.2.3.	Enviro	onmental exposure	controls							
		stance/mixture related asures to prevent exposure:								
	Structi exposi	ctural measures to prevent osure: Use modern equipment.								
	-	nisational measures nt exposure:	s to	Adapt the work process to the required working conditions of the work						
	Techni exposi	nical measures to p	revent	See Section 6						

SECTIO	SECTION 9. Physical and chemical properties									
9.1.	Information on basic physical and chemical properties									
		Value								
	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							
	Lover and upper explosion limit:	No information available	No information available							



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9.2.	Other information	NO INFORMATION AVAILABLE	
	Particle characteristics:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Solubility:	No information available	No information available
	Kinematic viscosity:	700-1000 cSt	No information available
	pH:	6.85 – 7.2	No information available
	Decomposition temperature:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Flash point:	No information available	No information available

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 condition				
10.3.	Possibility of hazardous reactions:	No information available.				
10.4.	Conditions to avoid:	No information available.				
10.5.	Incompatible materials:	No information available.				
10.6.	Hazardous decomposition products:	No information available.				

SECTIO	N 11. Toxic	ological information	on							
11.1. Information on toxicological effects										
	Acute toxic	city:								
Route of exposure:		Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time					
Oral:		No information available	-	LD ₅₀	No information available	-				
Dermal:		No information available	-	LD ₅₀	No information available	-				
Inhalatio	on:	No information available	-	LC ₅₀	No information available	-				



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	1		1						1			
Specific	target orgar	n toxicity	/ - single expo	sure (STOT-	-SE):							
		Spe	cific effects			Target	organ					
Oral:	No infor	mation	available		No inf	ormatio	on availab	ole -				
Dermal:	No infor	mation	available		No inf	ormatic	on availab	ole -				
Inhalation:	No infor	mation	available		Respir	atory sy	/stem	-				
	1			1								
Aspiratio	on hazard:		-									
Irritation	and corrosi	on										
			osure cu									
			me Sp	pecies	Evalua	ation	Metho	d				
Skin corrosion/iri	itation	-	-		-		-	No	informa	tion	availabl	e
Serious eye		_	_		_		_	No	informa	tion	availabl	•
damage/irritatior	า	-	-				-	INU	IIIOIIIIa	tion	avallabi	e
:												
Sensitiza	ation											
Skin sensitization	: No	information	tion available									
Respiratory	No	informat	tion available									
sensitization:												
Sympto	ms related to	nhysic	al, chemical, ar	nd toxicolo	aical n	ropertie	26					
Oral exposure:			r findings, che			-		roportic	os of tho	cubo	tanco h	ave not h
•		9	5	• • • •			.	•				
Dermal exposure	. Accordin	ig to ou	r findings, che	mical, phys	icai an			ropertie	es or the	subs	tance n	ave not b
Inhalation exposure:	Accordir	ng to ou	r findings, che	mical, phys	ical an	d toxic	ological p	oropertie	es of the	subs	tance h	ave not b
Eye exposure:	Accordir	na to ou	r findings, che	mical phys	ical an	d toxic	ological r	ronertie	es of the	suhs	tance h	ave not h
	/ lecor un	. <u></u>					eregicai p	noper ite		54.55		
Reneate	d dose toxic	ity (sub:	acute, subchro	nic chronic	-)							
Repeate			Exposure		-)							
	Dose		time	Species		Method	k	Evaluati	on l	Note		
	NI	. •	No	No		No		No				
Subacute oral	No inforn available	nation	information	informatio		informa		informa		-		
	avanabic		available	available		availabl		available	9			
Subacute	No inforn	nation	No	No		No		No	tion			
dermal	available		information available	informatio available		informa availabl		informa [:] available		-		
			No	No		No		No	-			
Subacute	No inform	nation	information	informatio		informa		informa	tion ·	-		
inhalation	available		available	available		availabl	le	available	e			



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

Specific target organ toxicity - repeated exposure (STOT-RE):

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)					
Carcinogenicity:	No information available				
Mutagenicity in-vitro:	No information available				
Genotoxicity:	No information available				
Mutagenicity in-vivo:	No information available				
Germ cell mutagenicity:	No information available				
 Reproductive toxicity:	No information available				



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	Summary of evaluation of the CMR No information available
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 informations:
	-

SECTION 12.	Ecological infor	mation					
12.1. Toxici	ty						
Acute (short-te toxicity	erm) Dose	Exposure time	Species	Me	ethod	Evaluation	Note
Fish	LC ₅₀	96 hours	-		ormation iilable	-	-
Crustacea:	EC ₅₀	48 hours	-	-	ormation iilable	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-		No information available		-
Other organism	ns: -	-	-	-		-	-
Chronic (long- toxicity	term) Doza	Exposure time	Species	Me	Method		Note
Fish	LC ₅₀	96 hours	-	No inforr available		-	-
Crustacea:	EC ₅₀	48 hours	-	No inforr available		_	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	No inforr available	No information available		-
Other organisr	ns: -	-	-	-		-	-
12.2. Persis	tence and degra	dability					
Abiot	ic degradation						
	Degradatior	half-lives	Metho	d		Evaluation	Note
Marine water	No informatior	available	No information a	No information available No in		No information available	
Fresh water	No informatior	available	No information a	available	No inforn	information available	



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T					DIOMO				Page 11	01 10
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Air	No inform	nation avai	lahle	Noir	nformation avai	ilahle	No inforr	nation a	available	_
Soil	No inform				formation ava		No inforr			_
				110 11						
Biod	egradation									
% Degradation	on T	ime (days)		Ν	Method		Evaluation		Note	e
-	No availab	inform le	ation	No infor available			information ailable	-		
12.3. Bioad	ccumulative	potential								
	nol-water p	•	efficien	nt (log Kov	w)					
Value	Concentr	ation	рΗ	°C	Method		Evaluation	n	No	te
-	No infor available	mation -		-	No informatio available		No informatic available		-	
Bioco	oncentratior	n Factor (B	CF)							
Value		Species			Method		Evaluation		Not	e
-	-			No in availa	formation able	-		-		
Chro	nic ecotoxic	:+./		:		1		:		
Val		Dose		Exposure time	Species	s	Method	Eva	aluation	Note
			o ormation ailable	No informatic available	on	No information available	No inforr availa	mation able	-	
Chronic toxicity on crustacea (Daphnia) EC ₅₀			o ormation ailable	No informatic available	on	No information available	No inforr availa	mation	-	



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	Noi	information availabl	e						
	Surf	ace tension:							
		Value	°C	Concentr	ation	Method	ł	Note	
	No avai	information lable	No information available	No informati available	on	No information	available	-	
	Ads	orption / desorptior	ו						
Transpo	ort	A/D coefficient Henry's constant	log Kow	Evaporati	on rate	Method	N	lote	
Soil-Wa	ater	No informatic available	on No informatio available	on No inform available	nation	No information available	-		
Water-	Air	No informatic available	on No informatio available	on No inform available	nation	No information available	-		
Soil-Air	-	No informatic available	on No information available	on No inform available	nation	No information available	-		
12.5.	Resu	ults of PBT and vPvE	assessment						
	Base	ed on available data	, the product does n	ot contain any	PBT or v	PvB substances.			
12.6.		ocrine disrupting pr	•						
	Base	ed on available data	, does not contain er	ndocrine disrup	otors.				
12.7.	Oth	er adverse effects							
	Noi	information availabl	e						
CECTIO	NI 13	Disassal sansidar							
13.1.		Disposal consider aste processing me							
13.1.1.	Pr	oduct/Packaging di	sposal:						
		Ibmit for disposal to otection.	o the legal person au	thorized by the	e Ministr	y of Environmental	and Natu	re	
13.1.2.	W	aste codes/waste d	esignations accordin	g to Low:					
	Di	sposal must be mad	de according to offici	al regulations.					



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13.1.3.	Waste tretment – relevar	nt information				
	No information available	·				
	-					
13.1.4.	Sewage disposal – releva	int information:				
	Waste must not be dispo	osed of into the sewage system.				
13.1.5.	Other disposal recomme					
	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 pro	ovisions:				
	Disposal must be made a	according to official regulations.				
SECTIO	N 14. Transport informati	on				
	Transporting/shipment by	road (ADR)				
UN num	ıber:	Not subject to transport regulations				
UN prop	per shipping name:	-				
Transpo	rt hazard class(es):	-				
Packing	group:	-				
Environ	mental hazards:	-				
Special	precautions for user:	-				
	Transporting/shipment by	rail (RID)				
UN num	ıber:	Not subject to transport regulations				
UN prop	per shipping name:	-				
Transpo	rt hazard class(es):	-				
Packing	group:	-				
Environ	mental hazards:	-				
Special	precautions for user:	-				
	Transporting/shipment by	inland waterways (ADN)				
UN num	ıber:	Not subject to transport regulations				
UN prop	per shipping name:	-				
Transpo	rt hazard class(es):	-				
Packing	group:	-				
Environ						



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Special precautions for user:	-
Transporting/shipment by sea (IN	MDG)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk condition in accordance with Annex II. of MARPOL 73/78 and IBC Codex:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Further information: -	

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



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Trade	name:	ame: BIOMOUNT AQUA						
Product code: BMA-X**			Date of compilation: 21 November 2022 Version: 5					
	Other EU	regulations:	Regulation (EC) No 1907/200 18 December 2006 concerni Restriction of Chemicals (RI amending Directive 1999/45/ and Commission Regulation 76/769/EEC and Commission 2000/21/EC; Directive 2004/42/CE of the Eu on the limitation of emission organic solvents in certain pai amending Directive 1999/13/E Council Directive 98/24/EC of of workers from the risks relat Regulation (EC) No 1272/2008 December 2008 on classific mixtures, amending and rep amending Regulation (EC) No COMMISSION REGULATION (Regulation (EC) No 1907/200 concerning the Registration Chemicals (REACH). REACH Restrictions on the ma dangerous substances, mixtur	ing the Registration, Evalu EACH), establishing a Euro EC and repealing Council Re n (EC) No 1488/94 as with Directives 91/155/EEC, 93 uropean Parliament and of the ns of volatile organic comp ints and varnishes and vehicle EC; 7 April 1998 on the protection red to chemical agents at wor 8 of the European Parliament tation, labelling and packa bealing Directives 67/548/EI 1907/2006; EU) 2020/878 of 18 June 202 D6 of the European Parliament n, Evaluation, Authorisatio	ation, Authoris pean Chemical gulation (EEC) ell as Council 8/67/EEC, 93/10 the Council of 21 ounds due to 1 e refinishing pro- on of the health rk; t and of the Cou- ging of substa EC and 1999/4 20 amending Ar- ent and of the n and Restrice	ation and s Agency, No 793/93 Directive 05/EC and April 2004 the use of oducts and and safety uncil of 16 ances and 5/EC, and mex II to Council ction of		
	Informati guideline	5	9/13/EC about limitation of er	nissions of volatile organic	compounds (VOC-		
	National	legislation:	Chemicals Act, Regulation of dangerous substances, Ord and on biological limit valu classification of waste with Ordinance on writing Mate Substances Act	linance on occupational ex les, Regulation on categor a waste catalog and list of	kposure limit v ies, types and f hazardous wa	alues aste,		
15.2.	Chemical	safety assessmer	nt					
	None							

SECTI	ON 16. Other information	
16.1.	Indication of changes:	-



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Trade	de name: BIOMOUNT AQUA						
Produ	oduct code: BMA-X** Date of compilation: 21 November 2022 Version: 5						
16.2.	Abbreviati acronyms:		ADR: Accord relatif au trans route (European Agreement Goods by Road) IMDG: International Maritime IATA: International Air Trans GHS: Globally Harmonised S EINECS: European Inventory of CAS: Chemical Abstracts Se DNEL: Derived No-Effect Lev LC50: Lethal concentration, LD50: Lethal dose, 50 perce PBT: Persistent, Bioaccumu vPvB: very Persistent and ver	Concerning the Internation Code for Dangerous Goods port Association System of Classification and L of Existing Commercial Chemi ervice (division of the America rel (UK REACH) 50 percent nt ilative and Toxic	al Carriage of I abelling of Che ical Substances	Dangerous	
16.3.	6.3. Key literature references and source of data:						
16.4.	Classificat 1272/2008	•	e used to derive the classifica	tion for mixture according	to Regulation	(EC)	
Classifi	cation		Classification procedure				
-			-				
16.5.	Relevant H	H statements (nur	nber and full text)				
	H: -		-				
16.6.	Training a	dvice:	-				
16.7.	Further in	formation:	** "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.				

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:	LEUKOGNC	LEUKOGNOST FIXATIVE			
	Chemical name:	-	-			
	Catalogue number:	LKF-X*				
1.2	Relevant identified use	es of the subs ⁻	tance or m	nixture and uses advised against		
	Uses:		For use i	n cytochemical diagnostics of leukemia.		
	Uses advised against:		Only the	identified uses are advised.		
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.			
1.3	Details of the supplier	Details of the supplier of the safety data sheet				
	Supplier:	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb			
	Telephone number:	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2404039			
	e-mail of competent p	erson:	msds@biognost.hr			
	National contact:		-			
1.4	Emergency telephone	Emergency telephone number				
	National Protection an	d Rescue Dire	ectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	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*:				



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Trading name:			LEUKOGNOST FIXATIVE					
Product code: LKF-X*		C	Date of compilation:	14 September 2022	Version:	2		
Hazard st	atements:	H225 H302 inhale H315 H317 H319 H336 H341 H350 P210	d. Causes skin irritation. May cause an allergic Causes serious eye irr May cause drowsiness Suspected of causing May cause cancer.	ful if swallowed, in contac skin reaction. itation. s or dizziness.				

		H350 May cause cancer.
	Precautionary statements:	 P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. P280 Wear protective gloves/protective clothing/eye/protection/face 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.
	Supplemetal hazard information (EU):	EUH066 Repeated exposure may cause skin dryness or cracking.
2.3	Other hazards	
	-	

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 aide	er: -			
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.			
4.3	Indication of any immediate m	edical attention and special treatment needed			

SECTI	SECTION 5. Firefighting measures					
5.1	Extinguishing media	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 su	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.		

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 c (see Section 8).	ase of inadequate ventilation use adequate airways protective equipment		
6.2	Environmental precautions:			
	Do not dispose of in sewage, c Protection and Rescue Directo	lrainage system and waterways. In case of large spillage contact National rate (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		
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).		
6.4	Reference to other sections			
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.			

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



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LKF-X*	Date of compilation:	14 September 2022 Version:	2		
	LKF-X*				

	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.		
			Secure proper ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:		-		
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. The	oroughly was	sh hands after work and before eating.		
7.2	Conditions for safe storage, including any incom	patibilities			
	Technical measures and storage conditions:	well ventilated storage rooms at temperatures range		Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.	
	Packaging materials:	Manufactu	rer's original packaging.		
	Requirements for storage rooms and vessels:		ep away from food and drink. Keep the containers htly closed.		
	Advices for storage equipment:	The storage must be made of hard material; must be resistant to chemicals. There must b that directly leads into sewage system. Secur ventilation.			
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).			
7.3	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	-			

SECTION 8. Exposure controls/personal protection							
8.1 Control parameters							
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values			
		ppm	mg/m ³				
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							
	Industrial						
Route of	Acute	Acute	Chronic	Chronic			
exposure:	effect local	effect systemic	effect local	effect systemic			
Oral	-			-			
Inhalation	1 mg/m3 (formaldehyde)	- 0.5 mg/m3 - (formaldehyde)		1210 mg/m ³ (acetone) 9 mg/m3 (formaldehyde)			
Dermal	-	- 0.037 mg/cm2 (formaldehyde)		186 mg/kg (acetone) 240 mg/kg (formaldehyde)			
Critical physical par	rameters: 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 prot	tection target	1	PNEC				
Fresh water			10.6 mg/l (acetone) 0.47 mg/l (formaldehyde)				
Freshwater sedime	nts		30.4 mg/kg (acetone) 2.44 mg/kg (formaldehyde)				
Marine water			1.06 mg/l (acetone) 0.47 mg/l (formaldehyde)				
Marine sediments			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 Exposure controls							



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8.2.1.	Appropriate engineering controls	5			
	Substance/mixture related measu prevent exposure during identifie		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.		
	Structural measures to prevent exposure:		In accordance with Section 7.		
	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent ex	posure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.		
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lowe levels of concentration in air; protective gas mask that covers th entire face in case of higher levels of concentration in air.			
8.2.2.2.	Skin protection				
	Hand protection:	Regul 374.F minSj	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374.Full contact: Glove material: butyl rubberGlove thickness: ≥ 0.50 mm Time until perforation: > 480 minSplash contact: Glove material: nitrile rubber Glove thickness: 0.4 mm Break through time: 35 min		
	Other skin protection:	suitabl cover t of imp	ing every day work use antistatic clothing (EN 13688) and able footwear, such as rubber boots (EN 20345) or shoes that er the entire foot. In case of spilling hazard, use clothing made npermeable material suitable for protection from liquid micals (Viton, PVC, himex) and footwear made from the same erial.		
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values (or becau ofinadequate ventilation), use a filter for organic vapors, ty "A"(boiling point >65°C) according to EN 14387.			
8.2.2.4.	Thermal hazards:	No info	ormation available		
8.2.3.	Environmental exposure controls	i			
	Substance/mixture related measures to prevent exposure:	See Se	ction 6		



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Product code: LKF-X [*]	Date of compilation:	14 September 2022 Version:	2							

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	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	
	Lover and upper explosion limit:	No information available	No information available	
	Flash point:	No information available	No information available No information available No information available	
	Auto-ignition temperature:	No information available		
	Decomposition temperature:	No information available		
	pH:	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			

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



10.6

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Tradir	ng name:		LEUKOGNOST	LEUKOGNOST FIXATIVE					
Produ	ıct code:	LKF-X*	Date of compilation:	14 September 2022 Version:	2				
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	Condition	s to avoid:	Avoid heat, sparks, ope	Avoid heat, sparks, open flames and other ignition sources.					
10.5	Incompati	ble materials:	No further relevant information available.						

Hazardous decomposition products: Carbon monoxide.

11.1 Inform	ation on toxicolog	ical effects					
	toxicity:						
Route of exposure:	Method	Species	Do	ose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure	time 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)	
Specif	ic target organ toxi	city – single ex	posure (S	TOT SE):			
	Specific effects			Target organ		Note	
Oral:	No informati	on available		No information available		-	
Dermal:	No informati	on available		No information available		-	
Inhalation:	No informati	No information available		No information available		may cause drowsiness or dizziness	
Aspira	tion hazard:		No inforr	mation available.			
Irritati	on and corrosion						
	Expos	ure time	Spec	ies Evaluatio	on Method	Note	
Skin corrosion/irrita	tion:		-	-	-	-	
Serious eye damage/irritati	on -		-	-	-	causes serious eye irritation	
Sensit	zation						
Skin sensitizatio	on: -						
Respiratory sen	sitization: -						



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Trading name:	LEUKOGNOST FIXATIVE							
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Oral exposure:	No informat	on available.				
Dermal exposure	e: No informat	on available.				
Inhalation expos	ure: No informat	on available.				
Eye exposure:	No informat	on available.				
Repeate	ed dose toxicity (sub	acute, subchro	onic, chronic)	1	-	
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-



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Trading	name:	LEUKOGNOST FIXATIVE							
Product	oduct code: LKF-X* Date o			Date of	f compilatio	n:	14 September 2022	Version: 2	
								1	
Subacut	Subacute oral No information available				No ir	formation available	-		
Subacut	e dermal	I	No information avail	able		No ir	formation available	-	
Subacut	e inhalatior	n I	No information avail	able		No ir	formation available	-	
Subchro	nic oral	1	No information avail	able		No ir	formation available	-	
Subchro	nic dermal	1	No information avail	able		No ir	formation available	-	
Subchro	nic inhalati	on l	No information avail	able		No ir	formation available	-	
Chronic	oral	1	No information avail	able		No ir	formation available	-	
Chronic	dermal	I	No information avail	able		No ir	formation available	-	
Chronic	inhalation	I	No information avail	able		No ir	formation available	-	
	CMR effects (carcinogenicity; mutagenicity; r					oxicity	()		
	Carcinogenicity:			Based on available data, the classification criteria are not met.					
	Mutagenic	ity <i>in v</i>	vitro:		Based on available data, the classification criteria are not met.				
	Genotoxici	ity:			Based on available data, the classification criteria are not met.				
	Mutagenic	ity <i>in v</i>	vivo:		Based on available data, the classification criteria are not met.				
	Germ cell r	mutag	enicity:		Based on available data, the classification criteria are not met.				
	Reproduct	ive tox	icity:		Based on available data, the classification criteria are not met.				
	Summary	of e	evaluation of the	CMR	Based on a	vailabl	e data, the classification	o criteria are not	
	properties:		_	met.					
3									
11.2.	Informatio	n on o	ther hazards:						
11.2.1.	Endocrine	disrup	ting properties:		÷				
	No known that affect		crine disrupting pro n health.	operties					
11.2.2.	Other info	rmatio	ns:						
	-								

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



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

Fish	LC ₅₀	96 hours	fish	No information available	>1,000 mg/l (acetone)	-
Crustacea:	EC ₅₀	48 hours	Daphnia magna	No information available	>1,000 mg/l (acetone)	-
Algae/aquatic plants	IC ₅₀	8 days	algae	No information available	>1,000 mg/l (acetone)	_
Other organisms	-	72 hours	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	_
Other organisms	_	_	_	_	_	_

12.2 Persistence and degradability

	No information available	No information available	No information available	-
Fresh water N			available	
	No information available	No information available	No information available	-
Air N	No information available	No information available	No information available	-
Soil N	No information available	No information available	No information available	-

% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-



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Tradin	ng nam	ne:						LEUK	OGNO	ST F	IXATIVE				
Produ	ct cod	e:	LKF-X	(*			Date o	of com	pilatior	า:	14 Sept	tember 2	2022	Version:	2
1															
12.3	Bioa	ccumi	ılative r	ootentia	1										
12.5	_		•			nt (log Kow)							
Valu			ncentra	1	pH		°C		ethod		Evalu	ation		Note	
_		No ir	format		-		-	No info	ormatior		No inform		-		
		availa	able					availab	le	ł	available				
	Bioc	oncen	tration	factor (BCF)										
\	Value			Specie	es		١	Vethoo	ł		Evaluati	on		Note	
No info		on	No		formati	on	No information			informati	on	-	formation		
availab	ole		availal	ole			available		available		available				
	Chro	onic ec	otoxici	ty											
	Val	ue		Dos	e	-	osure me	Spe	ecies	Μ	lethod	Evalu	uation	Note	
Chroni	c toxici	ity on	fish	LC ₅₀	ir	lo nfori vaila	mation able	No inforr availa	mation able		rmation lable	No informa availab		-	
Chroni	c tovici	itv on				lo		No		No		No			
crustac)	EC ₅₀		nfori vaila	mation able	inforr availa	mation able		rmation lable	informa availab		-	
				1	I			1		1		<u> </u>		I	
12.4	Mob	oility ir	n soil												
	Knov	wn or	predict	ed distri	ibution	in e	nvironm	nental c	compart	ment	s:				
			ation av	vailable											
			nsion:												
		/alue		°C		C	oncentra	ation		Me	thod			Note	
	No infor avail	matio able		o formatic ailable	on		informa ilable	tion	No inf availat		tion	-			



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

	Adsorption / desorption A/D coefficient				
Transpo	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-wa	ter No information available	No information available	No information available	No information available	-
Water-a	air No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-
12.5.	Results of PBT and vPvB asse	ssment			
	Based on available data, the	product does not o	contain any PBT or v	PvB substances.	
12.6.	Endocrine disrupting propert	ies			
	No known endocrine disrupt		affect the environm	nent.	
12.7.	Other adverse effects				
	No information available				
SECTIO	No information available N 13. Disposal consideration	15			
SECTIO 13.1		15			
13.1	N 13. Disposal consideration Waste treatment methods				
	N 13. Disposal consideration Waste treatment methods Product/Packaging disposa	ıl:			
13.1	N 13. Disposal consideration Waste treatment methods	ıl:	rized by the Ministr	y of Environmental	and Nature
13.1	N 13. Disposal consideration Waste treatment methods Product/Packaging disposa Submit for disposal to the	il: legal person autho		y of Environmental	and Nature
13.1	N 13. Disposal consideration Waste treatment methods Product/Packaging disposa Submit for disposal to the Protection.	il: legal person autho		y of Environmental	and Nature
13.1	N 13. Disposal consideration Waste treatment methods Product/Packaging disposa Submit for disposal to the Protection. Waste codes/waste design	al: legal person autho ations according to		y of Environmental	and Nature
13.1 13.1.1. 13.1.2.	N 13. Disposal consideration Waste treatment methods Product/Packaging disposa Submit for disposal to the Protection. Waste codes/waste design No information available	al: legal person autho ations according to		y of Environmental	and Nature
13.1.1. 13.1.1. 13.1.2. 13.1.3.	 N 13. Disposal consideration Waste treatment methods Product/Packaging disposal Submit for disposal to the Protection. Waste codes/waste design No information available Waste treatment – relevant No information available 	al: legal person autho ations according to : information:		y of Environmental	and Nature
13.1 13.1.1. 13.1.2.	N 13. Disposal consideration Waste treatment methods Product/Packaging disposa Submit for disposal to the Protection. Waste codes/waste design No information available Waste treatment – relevant No information available Sewage disposal – relevant	II: legal person autho ations according to : information:) Law:	y of Environmental	and Nature
13.1.1. 13.1.1. 13.1.2. 13.1.3.	 N 13. Disposal consideration Waste treatment methods Product/Packaging disposal Submit for disposal to the Protection. Waste codes/waste design No information available Waste treatment – relevant No information available 	II: legal person autho ations according to : information:) Law:	y of Environmental	and Nature



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

	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:			
	-				
	:				
SECTIO	N 14 TRANSPORT INFORM	MATION			
	Transporting/shipment by	road (ADR)			
UN num	ber:	1090			
UN prop	per shipping name:	Acetone			
Transpo	rt hazard class(es):	3			
Packing	group:	П			
Environr	mentally hazardous:	-			
Special p	precautions for user:	-			
	Transporting/shipment by	rail (RID)			
UN num	ber:	1090			
UN prop	per shipping name:	Acetone			
	rt hazard class(es):	3			
Packing	group:	П			
Environr	nentally hazardous:	-			
Special p	precautions for user:	-			
	Inland waterway transport	(ADN)			
UN num		1090			
UN prop	per shipping name:	Acetone			
	rt hazard class(es):	3			
Packing		11			
	nentally hazardous:	_			
	precautions for user:	-			
•	Transporting/shipment by	sea (IMDG)			
UN num		1090			
UN prop	per shipping name:	Acetone			
	rt hazard class(es):	3			
Packing					
-	nentally hazardous:	-			
	precautions for user:	_			



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Trading name:		LEUKOGNOST I	FIXATIVE		
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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (IC	CAO-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: -	

.1 Safety, health and en	ironmental regulations/legislation specific for the substance or mixture
EU regulations	
Authorization and/or	restrictions of use
Authorizations:	-
Restrictions:	-
Other EU regulations	 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/92 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 98/24/EC of 7 April 1998 on the protection of the health and safett 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 10 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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Trading name: Product code:		LEUKOGNOST FIXATIVE						
		LKF-X*		Date of compilation:	14 September 2022 Version: 2			
	National le	egislation:	dange and or classif Ordina	rous substances, Ordinanc n biological limit values, Re ication of waste with a was	ssification, packaging and labeling of e on occupational exposure limit values egulation on categories, types and ete catalog and list of hazardous waste, fety data sheet, Transport of Hazardous			
15.2	Chemical	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)				
Classifi	cation C	Classification procedure			
-	-				
16.5.	Relevant H statements (number and full text)				



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Tradin	Trading name:		LEUKOGNOST FIXATIVE							
Product code:		LKF-X*		Date of compilation:	14 September 2022	Version:	2			
	H:	225 301+ 302 314 315 317 319 332 336 341 350 EUH0	-311+331	Toxic i Harmf Harmf Cause Cause May ca Cause Harmf May ca Susped May ca	flammable liquid and vap f swallowed, in contact wit ul if swallowed. ul in contact with skin. s severe skin burns and ey s skin irritation. ause an allergic skin reacti s serious eye irritation. ul if inhaled. ause drowsiness or dizzine cted of causing genetic de ause cancer. ted exposure may cause s	th skin and if inhaled. e damage. on. ess. efects.				
16.6.	Training advice:			-						
16.7.	Further information:			-						

ANNEX: Exposure scenario resulting to chemical safety assessment



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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 SUB	STANCE/M	XTURE AND OF THE COMPANY/UNDERTAKING			
1.1.	Product identifier						
	Trading name:	LEUKOGN	LEUKOGNOST HEM				
	Chemical name:	-					
	Catalogue number:	LKH-OT-X	LKH-OT-X**				
1.2.	Relevant identified uses of the substance or mixture and uses advised against						
	Uses: Hematoxylin reagent for use with LeukoGnost kits.						
	Uses advised against:		Only the i	dentified uses are advised.			
Reason why uses advised against: medical device, registered at the Agency for				uct is intended for use only as an <i>in vitro</i> diagnostic levice, 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: Bi		BioGnost Ltd.				
	Address:	Ν	Medjugorska 59, Zagreb				
	Telephone number: +		+385 1 2409997				
	Fax no.: +		+385 1 2404039				
	e-mail of competent p	erson: <u>r</u>	<u>msds@biognost.hr</u>				
	National contact:	-	-				
1.4.	Emergency telephone	number					
	National Protection an	d Rescue Di	rectorate:	112			
	Medical information:			+385 1 2348 342			
	Other information:			-			

SECTIO	SECTION 2 HAZARDS INFORMATION					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification (REGULATION ((EC) No. 1272/2008	(CLP)			
	Hazard class and cate	egory code:	Hazard statements*:			
	Acute Tox. 4		H302			
2.1.2.	Additional information					
	-					
*For ful	l text of Hazard- and EU Hazar	d-statements: see S	Section 16			
2.2.	Label elements					
	Product 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 Prop	erties:						
	No known endocrine disrupt	ing properties						
	Results of PBT and vPvB as PBT or a vPvB.	Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a						

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

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



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Trading name:	LEUKOGNOST HEM							
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 ai	der:	Treat symptomatically.		
4.2.	Most important symptoms a	nd effe	ects, both acute and delayed		
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perime may cause coughing, sneezing, headache and nausea.			
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. term exposure may cause drying, cracking and tingling sensation of s			
	Following eye contact:		t eye contact may cause slight to moderate irritation, lacrimation and ng sensation. If the symptoms persist, immediately call a physician.		
	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the burning sensation; higher levels of concentration may cause nause abdominal pain and vomiting. In case of vomiting, aspiration cause coughing, difficult breathing. Higher levels of concentration may cause suffocation.			
4.3.	Indication of any immediate	medica	al attention and special treatment needed		
	-				

SECTIO	CTION 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 of Cool closed containers exposed to	compressed air breathing apparatus and fireproof clothing. fire with water spray or vapor.			
5.4.	Additional information				
	Remove sources of heat and igniti Do not contaminate the environm				

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



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					Paye 4		
g name:			LEUKOGN	NOST HEM			
ct code:	LKH-OT-X**	Revisio	n date:	03 April 2023	Version:	2	
Accident	prevention methods	:: membe	rs without	protective equipment			
Emergeno	y procedures:	Mark th	e area usin	g proper signs.			
For emerg	gency responders:						
Wear pro	tective equipment (s	see Section 8).					
Environm	ental precautions:						
Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact Na Protection and Rescue Directorate (NPRD) on 112.					National		
Methods	and material for cor	ntainment and clea	aning up				
Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste 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 legender persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and inverted with water				e material n well he legal e			
Other info	ormation:	-					
Reference to other sections							
			5	quipment.			
See Section	on 13 for informatio	n about containm	pout containment.				
	Accident p Emergence For emergence Wear prote Environme Do not dis Protection Methods Bunding, capping p Cleaning of Other info Reference See Section	ct code: LKH-OT-X** Accident prevention methods Emergency procedures: For emergency responders: Wear protective equipment (s Environmental precautions: Do not dispose of in sewage, Protection and Rescue Director Methods and material for cor Bunding, covering of drains; capping procedures: Cleaning up: Other information: Reference to other sections See Section 7 for information See Section 8 for information	ct code:LKH-OT-X**RevisioAccident prevention methods:Evacuat membes sparks aEmergency procedures:Mark theFor emergency responders:Mark theFor emergency responders:Wear protective equipment (see Section 8).Environmental precautions:Do not dispose of in sewage, drainage system a Protection and Rescue Directorate (NPRD) on 1Methods and material for containment and clear Bunding, covering of drains; capping procedures:Sand or clay barCleaning up:Where possible, material (sand, co in tightly closed ventilated storage persons authoriz Protection. After materials with wOther information:-Reference to other sectionsSee Section 7 for information about secure han See Section 8 for information about personal p	Ct code:LKH-OT-X**Revision date:Accident prevention methods:Evacuate members members without sparks and ignitiorEmergency procedures:Mark the area usinFor emergency responders:Wear protective equipment (see Section 8).Environmental precautions:Do not dispose of in sewage, drainage system and waterwe Protection and Rescue Directorate (NPRD) on 112.Methods and material for containment and cleaning upBunding, covering of drains; capping procedures:Cleaning up:Sand or clay barriers.Cleaning up:Where possible, the substa material (sand, diatomaceo in tightly closed impermeat ventilated storage rooms u persons authorized by the I Protection. After disposal o materials with water.Other information:-Reference to other sectionsSee Section 7 for information about secure handling.	ct code: LKH-OT-X** Revision date: 03 April 2023 Accident prevention methods: Evacuate members of all non-essential members without protective equipment sparks and ignition. Do not smoke. Emergency procedures: Mark the area using proper signs. For emergency responders: Wear protective equipment (see Section 8). Environmental precautions: Do not dispose of in sewage, drainage system and waterways. In case of large sp Protection and Rescue Directorate (NPRD) on 112. Methods and material for containment and cleaning up Bunding, covering of drains; capping procedures: Cleaning up: Sand or clay barriers. Venter possible, the substance can be absorbed b material (sand, diatomaceous earth, vermiculite). If in tightly closed impermeable containers. Store th ventilated storage rooms until disposal. Submit for persons authorized by the Ministry of Environmer Protection. After disposal of the products, wash th materials with water. Other information: - Reference to other sections - See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment.	g name: LEUKOGNOST HEM ct code: LKH-OT-X** Revision date: 03 April 2023 Version: Accident prevention methods: Evacuate members of all non-essential personnel members without protective equipment. Remove all sparks and ignition. Do not smoke. Emergency procedures: Mark the area using proper signs. For emergency responders: Wear protective equipment (see Section 8). Environmental precautions: Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact Protection and Rescue Directorate (NPRD) on 112. Methods and material for containment and cleaning up Bunding, covering of drains; capping procedures: Cleaning up: Sand or clay barriers. Versions authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and an materials with water. Other information: - Reference to other sections See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment.	

SECTIO	N 7 HANDLING AN STORAGE						
7.1.	Precautions for safe handling						
7.1.1.	Protection measures						
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.					
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.					
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.					
	Other measures:	-					
7.1.2.	Advice on general occupational hygiene:						
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.						
7.2.	Conditions for safe storage, including any incompat	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 EX	KPOSU		TROLS/PER	SONAL	PROTECTION						
8.1. Cont	rol para	meters	eters								
Subs		CAS No			exposure limit term values	Biological limit values					
					ppm	mg/m ³					
Ethylene glycol 107-21-1				-1	20/40	52/104	No infor	mation available			
Substance											
EC No: - CAS No				-							
DNEL											
					Industrial						
Route of		A	cute		Acute	e Chronic		Chronic			
exposure:		effe	ct local	effe	ect systemic	effect local		effect systemic			
Oral		-		-		-		-			
Inhalation						35 mg/ kg (ethylene gly	col)				
Dermal 106 mg/kg (ethylene glycol)											
Critical physic	al parar	neters: s	olubility, flar	nmabili	ty, corrosivity:	-					
					Consumer						



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Trading r	name:				LEUKOG	SNOST HEM				
Product o	code:	LKH-OT-X**	F	Revisio	n date:	03 April 2023	Version:	2		
Route of exposure:	:	Acute effect local	effe	Acute ect syst		Chronic effect local	Chronic effect systemic			
Oral		-	-			-	-			
Inhalation		-	-			7 mg/kg (ethylene glycol)	-			
Dermal		-	-			-	53 mg/kg (glycol)	ethylene		
PNEC						·				
Environme	ental pro	otection target			PNEC					
Fresh water					10 mg/l	(ethylene glycol)				
Freshwate	er sedime	ents			37 mg/k	g (ethylene glycol)				
Marine wa	ater				1 mg/l (e	ethylene glycol)				
Marine sediments					3.7 mg/k	g (ethylene glycol)				
Food chaii	n				No information available					
Microorga	anisms ir	n sewage treatment			199.5 mg	g/l (ethylene glycol)				
Soil (agricultural)					1.53 mg/	'kg (ethylene glycol)				
Air					No infor	mation available				
8.2.	Fxpos	sure controls								
8.2.1.	· · ·	eering measures								
<u></u>	Subst meas	ance/mixture related ures to prevent expo g identified uses:			•	n well ventilated room ot eat, drink or smoke i	•	•		
	Struct expos	tural measures to pr sure:	event N	No information available						
	-	nisational measures ent exposure:		0	ation of w work proce	ork in order to reduce	other worker's	influence		
	Techr expos	nical measures to pre sure:		•	•	rkspace ventilation in o els in air below permitt	•			
8.2.2.	Perso	nal protection equip	oment							
8.2.2.1.	Eye a	nd face protection:		afety g visor.	lasses tha	t stick to face (prevent	ing splashing)	(EN 166) or		
8.2.2.2.	Skin p	protection								
	Hand	protection:		Glove m Glove th	naterial: ni nickness: ≥	e according to standard trile rubber ±0.11 mm ne: >480 min	l EN 374.			



Technical measures to prevent

exposure:

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Trading	name:			LEUKOGNOST HEM							
Product	code:	LKH-OT-X**		Revision date: 03 April 2023 Version:							
()ther 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.	Respir	ratory protection:	filter f	rotective full face mask (EN 136) or half mask (EN 140) equipped with a ter for organic vapors, type "A" (boiling point >65°C) acording to EN 4387) used when concentration levels exceed GVI.							
8.2.2.4.	Therm	al hazards:	No inf	formation available							
8.2.3.	Enviro	nmental exposure	controls								
		ance/mixture relate ures to prevent exp		See Section 6							
	Struct expos	ural measures to p ure:	revent	Use modern equipment.							
		iisational measures nt exposure:	to	Adapt the work pr workplace.	Adapt the work process to the required working conditions o workplace.						
		•		- F							

See Section 6

1.	Information on basic physical and che	nical 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				
	Lover 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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Trading	Trading name: LEUKOGNOST HEM							
Produc	t code:	LKH-OT-X**	Revision date:	03 April 202	23	Version:	2	
		• • •		••				
	Particle ch	aracteristics:	No information a	vailable	No into	ormation avai	lable	
9.2.	Other info	rmation						

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 INFORM	ATION			
11.1. Informatio	n on hazard classes as	defined in Reg	gulation (EC) No 1272	2/2008	
Acute toxic	city:				
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 ta	rget organ toxicity – si	ngle exposure	(STOT SE):		
	Specif	ic effects	Target	organ	Note
Oral exposure:	No information	available	No informatio	-	
Dermal exposure:	No information	available	No informatio	n available	-
Inhalation exposure	: No information	available	No informatio	n available	-
Respirator	y irritation:	No info	ormation available		
Irritation a	nd corrosion				
Ĩ	Exposure time	Species	Evaluation	Method	Note



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Trading name:			LEUKOG	NOST HEM		
Product code:	LKH-OT-X**	Re	evision date:	03 April 202	23 Version:	2
Skin irritation:	-	rabb	it -	-	Slight irritatic glycol)	on (ethylene
Eye irritation:	rabb	it -	-	Slight irritatic glycol)	on (ethylene	
Sensitiz						
Dermal exposure Inhalation		avaliable				
exposure:	No information	available				
Sympto	ms related to the pl	nysical, chemic	al and toxicolog	gical characterist	ics	
Oral exposure:	No informat					
Dermal exposure						
Inhalation expos						
Eye exposure:	Causes serio	us eye damage	9			
Repeate	ed dose toxicity (sub	acute, 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:					LEUK	(OGI	NOST HEM			
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Chronic dermal		lo information No vailable availa		No mation information able available		on	No information available	No in availa	formation able	-
Chronic inhalation	No information Available available			-	No informatio available	on	No information available	No in availa	oformation able	-
1										
Specifie	target	t organ toxicit	y – repeat	ed e	xposure (ST	TOT F	RE):			
		S	pecific effe	ects			Target orga	n		Note
Subacute oral	acute oral No information						nformation avai		-	
Subacute derma	Subacute dermal No information					No i	nformation avai	lable	-	
	Subacute inhalation No information						nformation avai		-	
Subchronic oral No information							nformation avai		-	
Subchronic dermal No information						o information available		-	-	
Subchronic inhalation No information						No information available		-		
Chronic oral No information									-	
Chronic dermal		No informa					nformation avai		-	
Chronic inhalati	on	No informa	ation availa	able		No i	nformation avai	lable	-	
CMD -	· · · · · / ·									
		carcinogenicit						dicata		offorto
Carcino		-					nimals did not in		_	enects.
Genoto		in-vitro:			mation avail		d not indicate r	nutage	nic enects.	
	,	in-vivo:					d not indicate n	nutanar	nic offorts	
J	·····	agenicity:			nation avail			nutagei	ne encets.	
		toxicity:		oxic			ctive organs w	as dete	ermined in	reproductive
Summa	ary of e	valuation of t	he CMR pr	ope	rties: -					
11.2. Informa	ation o	n other hazar	ds:							
11.2.1. Endocr	ine disr	rupting prope	erties:							
	ties tha	endocrine It affect huma	disruptir n health.	ng						
11.2.2. Other i	nforma	itions:								
-										



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Trading name:	LEUKOGNOST HEM					
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12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Fish	No information available	72.860 mg/l (ethylene glycol)	-
Crustacea:	EC ₅₀	48 hours	water flea	No information available	>100 mg/l (ethylene glycol)	-
Algae/aquatic plants	IC ₅₀	8 days	algae	No information available	6.500-13.000 mg/l (ethylene glycol)	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	_
Other organisms	-	_	_	_	_	-

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

Biodegradation						
% Degradation	Time (days)	Method	Evaluation	Note		
No information available	No information available	No information available	No information available	No information available		



Page 12 of 16 Trading name: **LEUKOGNOST HEM** Product code: LKH-OT-X** Revision date: 03 April 2023 Version: 2 12.3. Bioaccumulative potential Partition coefficient: n-octanol/water (log Kow): °C Value Concentration Method Evaluation pН Note No information No information No information _ _ _ available available available **Bioconcentration factor (BCF)** Value Method Evaluation Note **Species** No information No information No information No information No information available available available available available Chronic ecotoxicity Exposure Value Dose Species Method Evaluation Note time No No No No information LC_{50} Chronic toxicity on fish information information information _ available available available available No No No No information Chronic toxicity on information information information EC_{50} _ crustacea (Daphnia) available available available available 12.4. Mobility in soil Known or predicted distribution in environmental compartments: No information available Surface tension: °C Value Concentration Method Note No No No information No information information information available available available available



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SAFETY DATA SHEET 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

Transpo	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-wa	ter 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	Soil-air No information No information No information available available available -				-
12.5.	Results of PBT and vPvB asse	scmont			
12.3.	Based on available data, the		contain any PBT or y	PVB substances	
12.6.	Endocrine disrupting propert	ies			
	No known endocrine disrupting properties that affect the environment.				
		51 - 1			
12.7.	. Other adverse effects				
	No adverse effects are expected.				
	1				
SECTIC	N 13 DISPOSAL CONSIDERA	TIONS			
13.1.	Waste treatment methods				
13.1.1.	Product/Packaging disposa	l:			
	Submit for disposal to the Protection.	egal person autho	rized by the Ministr	y of Environmental ar	nd Nature
13.1.2.	Waste codes/waste design	ations according to) Law:		
	No information available				
		information			
13.1.3.	Waste treatment – relevant	information.			
13.1.3.	Waste treatment – relevant No information available	information.			
13.1.3.					



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Trading I	name:		LEUKOG	SNOST HEM	
Product	code:	LKH-OT-X**	Revision date:	03 April 2023	Version: 2
13.1.5.	Other di	sposal recommenda	tions:		
			ct's remains into the sewa charge. Do not dispose o		remains to the collectors ne sewage system. Submit
	•	aging to the collecto may occur.	ors authorized by the mini	stry in charge. Do not	dispose of in places where
13.1.6.	Relevant	Community provision	ons:		
	-				
SECTION	14 TRAN	ISPORT INFORMAT	ION		
Т	ransporti	ng/shipment by road	d (ADR)		
UN numb	er:		Not subject to transpo	rt regulations.	
UN prope	r shipping	g name:	-		
Transport	hazard cl	ass(es):	-		
Packing g	roup:		-		
Environm	entally ha	zardous:	-		
Special pr	ecautions	for user:	-		
Т	ransporti	ng/shipment by rail	(RID)		
UN numb	er:		Not subject to transpo	rt regulations.	
UN prope	r shipping	g name:	-		
Transport	hazard cl	ass(es):	-		
Packing g	roup:		-		
Environm	entally ha	zardous:	-		
Special pr	ecautions	for user:	-		
l	nland wat	erway transport (AD	N)		
UN numb	er:		Not subject to transpo	rt regulations.	
UN prope	r shipping	g name:	-		
Transport	hazard cl	ass(es):	-		
Packing g	roup:		-		
Environm	entally ha	zardous:	-		
Special pr	ecautions	for user:	-		
Т	ransporti	ng/shipment by sea	(IMDG)		
UN numb	er:		Not subject to transpo	rt regulations.	
UN prope		-	-		
Transport	hazard cl	ass(es):	-		
Packing g			-		
Environm	entally ha	zardous:	-		



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

Special precautions for user:	-
Transporting/shipment by a	ir (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 produ	uct is not subject to classification.

15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorization and/or rest	rictions 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 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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Tradin	g name:		LEUKOG	NOST HEM		
Produc	ct code:	LKH-OT-X**	Revision date:	03 April 2023	Version:	2
	National	legislation:	Chemicals Act, Regulation of dangerous substances, Ordi and on biological limit value classification of waste with a Ordinance on writing Mater Substances Act	inance on occupation es, Regulation on cate a waste catalog and li	al exposure limi egories, types ar st of hazardous	t values nd waste,
15.2.	Chemical	safety assessmen	t			
	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		
16.3.	Key literature references and source of data:	-		
16.4.	Classification and procedure u 1272/2008 (CLP)	sed to derive the classification for mixture according to Regulation (EC)		
Classifi	cation	Classification procedure		
-		-		
16.5.	Relevant H statements (numb	er and full text)		
	H: 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

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