

Page 1 of 17

Trading name:		BIOFI	X GL		
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

SECTIO	ON 1. Identification of t	he substa	nce/mixture	and of the company/undertaking		
1.1.	Product identifier					
	Trading name:	BIOFIX G	iL			
	Chemical name:	-				
	Catalogue number:	BFGL-X*	*			
1.2.	Relevant identified use	s of the su	ıbstance or n	nixture and uses advised against		
	Uses:		For use	in histology.		
	Uses advised against:		Only the	e identified uses are advised.		
	Reason why uses advis	ed against:  The product is intended for use only as an <i>in vitro</i> diagnostic medical device and there is no reason to use it for other purposes				
1.3.	Details of the supplier	of the safe	ety data shee	t		
	Supplier:		BioGnost Ltd	BioGnost Ltd.		
	Address:		Medjugorsk	a 59, Zagreb		
	Telephone number:		+385 1 2409997			
	Fax no.:		+385 1 2404039			
	e-mail of competent p	erson:	msds@biognost.hr			
	National contact: -		-			
1.4.	Emergency telephone number					
	National Protection and Rescue Directorate		Directorate:	112		
	Medical information:			+38512348342		
	Other information:			-		

SECTIO	TON 2. Hazards information				
2.1.	Classification of substance or mixture				
2.1.1.	Classification according to Reg	ulation (EC) No	1272/2008 (CLP)		
	Hazard class and categ	ory code:		Signal word:	
	Flam. Liq. 3		H226		
	Skin Sens. 1		H317		
	Muta. 2		H341		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazard-	statements: see	e Section 16		
2.2.	Label contents				
	Product identification:	BIOFIX GL			
	Identification number:	-			
	Authorisation number:	-			



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

Page 2 of 17

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

	Hazard pictograms:	GHS02  GHS07  GHS08
	Signal word:	Danger
	Hazard statement:	<ul><li>H226 Flammable liquid and vapour.</li><li>H317 May cause an allergic skin reaction.</li><li>H341 Suspected of causing genetic defects.</li></ul>
	Precautionary statement:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not smoke. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P308 + P313 IF exposed or concerned: Get medical advice/attention.
	Supplemental hazard information (EU):	-
2.3.	Other hazards	
	Endocrine Disrupting Property No known endocrine disrupt Results of PBT and vPvB as PBT or a vPvB.	

SECTION 3. Comp	SECTION 3. Composition/information on ingredients					
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Name	Classification according to Regulation (EC) No 1272/2008 (CLP)		
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610- 43-xxxx	7 –10 %	ethanol	Flam. Liq. 2; H225		



amended by Regulation (EU) No. 2020/878

**Page 3 of 17** 

Trading name:		BIOFI	X GL	•	
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

SECTI	ON 4. First aid measures			
4.1.	Description of first aid me	easures		
	General notes:		If the symptoms remain, immediately call a physician.	
	Following inhalation:		Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. Provide oxygen if difficult breathing occurs.	
	Following skin contact:		Remove the contaminated clothes. Carefully rinse with water for 15 minutes.	
	Following eye contact:		Rinse the eyes with a mild stream of water for at least 15 minutes with eyelids wide open.	
	Following ingestion:		Thoroughly rinse mouth with water. If the afflicted person is conscious, provide them with copious amounts of water. Seek medical assistance.	
	Self-protection of the firs	t aider:	-	
4.2.	Most important symptoms and effects, both acute and delayed			
	Following inhalation:	irritation).	e eye and upper respiratory system irritation (burning sensation, May cause bronchoconstriction. Symptoms may include headache, drowsiness and loss of consciousness after exposure to high ation.	
	Following skin contact:	Defatting,	, dry skin.	
	Following eye contact:	Splashing may cause sensation of discomfort, burning sensation, conjunctival redness, superficial corneal lesions.		
	Following ingestion:	drowsines	s may include strong stinging sensation, headache, dizziness, and loss of consciousness after exposure to high concentration. In enaturants present, dispepsion may occur (such as vomiting).	
4.3.	Indication of any immedi	ate medical	attention and special treatment needed	
	No information available			

SECTIO	SECTION 5. Firefighting measures				
5.1.	Extinguishing media				
	Suitable extinguishing media:	Small fire - water spray, dry powder, alcohol-resistant foam, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam			
	Unsuitable extinguishing media:	Water jet			
5.2.	Special hazards arising from the substance or mixture				



Page 4 of 17

Trading name:		BIOFI	X GL		
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

	Hazardous combustion products: Incomplete combustion of the product.
5.3.	Advice for firefighters
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.  Cool the closed containers that have been exposed to fire using water spray or steam.
5.4.	Additional information
	-

SECTIO	SECTION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment:	contained breatl	lothes while disposing of smaller amounts. Use self- ning apparatus with compressed air (open circuit) in g of larger quantities, or a self-contained breathing closed circuit.		
	Accident prevention methods:	emergency cont	area, remove all ignition sources and in case of act 112, manufacturer, and distributor. Place warning symbols and devices that cause sparking.		
	Emergency procedures:	Remove or neutralize all the factors that may worsen the situation, use all the approved means for controlling the situation and use all the recommended personal protection.			
6.1.2.	For emergency responders:				
	Use only a self-contained open-	circuit compressed	l air breathing apparatus and fireproof clothing.		
6.2.	Environmental precautions:				
	Use sand barriers for preventing system and waterways.	further spillage of	chemicals. Do not dispose of in sewage, drainage		
6.3.	Methods and material for conta	inment and cleanir	ng up		
6.3.1.	Bunding, covering of drains; cap	ping procedures:	Sand barriers or barriers made of similar material.		
6.3.2.	Cleaning up:		Sawdust, sand, mineral adsorbents.		
6.3.3.	Other information:		Secure proper ventilation. Contact the responsible person; in case of larger spills and danger of environmental pollution contact 112.		
6.4.	Reference to other sections	Reference to other sections			
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.				

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



Page 5 of 17

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

7.1.1.	Protection measures				
	Measures to prevent fire:		Keep away from sources of ignition and heat. Do not use tools that cause sparking.		
	Measures to prevent aerosol and dust gene	eration:	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:	Advice on general occupational hygiene:			
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.				
7.2.	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:		Keep in a well-ventilated place. Keep away from sources of heat and solar radiation.		
	Packaging materials:	Ma	Manufacturer's original packaging.		
	Requirements for storage rooms and vesse	ıc.	Keep away from food and drink. Keep the containers tightly closed.		
	Advices for storage equipment:	be dir	e storage must be made of hard material; floors must resistant to chemicals. There must be no drain that ectly leads into sewage system. Secure proper ntilation.		
	Further information on storage conditions:	: -			
7.3.	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	-			

SECTIO	SECTION 8. Exposure controls/personal protection								
8.1.	Cont	ontrol parameters							
	Substance CA		CAS N			Occupational exposure limit values/short term values Biol		ological limit values	
						ppm	mg/ı	m <sup>3</sup>	
ethanol	ethanol 64			64-17	-5	1000/-	1900	)/-	-
Substan	ce:	-							
EC No:		-		CAS No	_				
DNEL									
	Industrial								
Route o	Route of		Acute	Acute			Chronic	Chronic	
exposui	re:		effe	ect local	ef	fect systemic	e	ffect local	effect systemic
Oral			-		-		-		-



Page 6 of 17

						Page 6 of	<u> 17 </u>
Trading r	name:		_	BI	OFIX GL	_	
Product	code:	BFGL-X**	Date of cor	mpilation:	12.11.2022.	Version:	2
Inhalation	1				35 mg/kg (ethylene glycol)	950 mg/m³	(ethanol)
Dermal		-	-		-	343 mg/kg (	(ethanol)
Critical ph	nysical para	meters: solubility, fla	ammability, cor	rosivity:			
			Cor	nsumer			
Route of exposure	:	Acute effect local	Acut		Chronic effect local	Chro effect sy	-
Oral		-	-		-	-	<u> </u>
Inhalation	1	-	-		-	114 mg/m <sup>3</sup>	(ethanol)
Dermal		-	-		-	206 mg/kg (	
PNEC							
Environmental protection target PNEC							
Fresh wat	er			0.96 mg/l (ethanol)			
Freshwate	er sediment	ts		36 mg/kg (ethanol)			
Marine wa	ater			0.79 mg/l (ethanol)			
Marine se	diments			No information available			
Food chai	n			No infor	mation available		
Microorga	anisms in s	ewage treatment		No information available			
Soil (agric	cultural)			0.63 mg/	/kg (ethanol)		
Air				No infor	mation available		
8.2.	Exposur	e control					
8.2.1.	Approp	riate engineering co	ntrols				
		nce/mixture related r exposure during ide			Use personal protective equipment. Do not eat, drink or smoke in the workspace.		
	Structur	al measures to prev	ent exposure:	No	information available	9	
Organisational measures to prevent exp		prevent exposi	Organization of work in order to reduce other				
	Technic	Technical measures to prevent exposure:			See Section 7.2		
8.2.2.	Persona	I protective equipm	ent				
8.2.2.1.	Eye and	Protective eyeglasses that stick to face, or a visor in concentration in air; protective mask that covers the case of higher concentration in air.					
8.2.2.2.	Skin pro	otection	ii				
	- ····     - · · · · · · · · · · · · ·						



**Page 7 of 17** 

Trading name:	BIOFIX GL			•	
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

	Hand protection:	of contact with drops use polych	butyl rubber gloves (0.4 mm thick). In case alorin gloves (0.1 mm thick).  ding to the EU Directive EU 2016/425/EEC			
	Other skin protection:	During everyday work use cotton clothing and suitable footwear, such as rubber boots or shoes that cover the entire foot. In case of spilling hazard use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.				
8.2.2.3.	Respiratory protection:	In case of concentration higher t filter.	han GVI, use full face mask with brown A			
8.2.2.4.	Thermal hazards:	No information available				
8.2.3.	Environmental exposure	controls				
	Substance/mixture relate	d measures to prevent exposure:	See Section 6			
	Structural measures to pr	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 pr	event exposure:	See Section 6			

.1.	Information on basic physical and che	mical properties	
		Value	Method
	Physical state:	Liquid	No information available
	Color:	light yellow	No information available
	Odour/odour threshold:	sharp/no information availabel	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:	55°C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	рН:	6.2 – 6.8	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available



Page 8 of 17

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
	-		

SECTIO	SECTION 10. Stability and reactivity			
10.1.	Reactivity:	The product is stable under normal working and storage conditions.		
10.2.	Chemical stability:	The product is stable under standard ambient conditions of storing and using (room temperature).		
10.3.	Possibility of hazardous reactions:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.		
10.4.	Conditions to avoid:	High temperatures, ignition sources, open flame.		
10.5.	Incompatible materials:	Oxidants, acids, alkali metals.		
10.6.	Hazardous decomposition products:	Nonbiodegradable in case of using in the described way.		

SECTIO	N 11. To	cicological informa	ation						
11.1.	Informat	tion on hazard class	es as defined	in Regula	ition (EC	C) No 1272/2008			
	Acute to	xicity:							
Route o		Method	Species	Do LD <sub>50</sub> /L	ctive ose .C <sub>50</sub> or	Exposure time		Results	
Oral:		No information available	rat	LD <sub>50</sub>		-		50 mg/kg (ethanol) 00 mg/kg (glyoxal)	
Dermal:		No information available	rabbit	LD <sub>50</sub>		-	>20.000 mg/kg (ethanol) 10.000 mg/kg (glyoxal)		
Inhalati	on:	No information available	rat	LC <sub>50</sub>		4 h (ethanol)		000 (ethanol) I mg/l (glyoxal)	
	Specific	target organ toxicit	y – single expo	osure (ST	OT SE):				
		Spe	ecific effects			Target organ		Note	
Oral:		No informati	ion available No info		No information available		-		
Dermal:		No informati	on available		No info	ormation available	· -		



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

amended by Regulation (EU) No. 2020/878

				Page 9 of	f 17
Trading name:		BIOF	IX GL		
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

Inhalation:	No infor	mation availab	ole	No info	ormation avai	ilable -	
Respira	tory irritation:		May caus	e respirat	ory system ir	ritation.	
Irritatio	n and corrosion						
miduo		sure time	Species	Fvalu	ation M	ethod	Note
Skin corrosion/irritati	_		-	-	_		uses skin irritations.
Serious eye damage/irritatio	n -		_	-	-	No ava	information ilable
Sensitiz		N					
Skin sensitization			tion availab				
Respiratory syste	em sensitization:	No informa	tion availab	ie			
Sympto	oms related to th	e physical, che	emical and t	oxicologi	cal characteri	stics	
Oral exposure:	of consci		exposure to	high con			drowsiness and loss curants present,
Dermal exposure	e: Defatting	g, dry skin.					
Inhalation expos	sure: cause br		tion. Sympto	oms may	include head	ache, dizziness	on, irritation). May , drowsiness and
Eye exposure:	Splashing		ensation of				nctival redness,
Repeate	ed dose toxicity			onic)			
	Dose	Exposur time	e Spe	cies	Method	Evaluation	Note
Subacute oral	No informat available	ion No informat available		rmation lable	No information available	No informatio available	on -
Subacute dermal	No informat available	ion No informat available		rmation lable	No information available	No informatic available	n -
Subacute inhalation	No informat	ion No informati available		rmation lable	No information available	No information available	n -



Reproductive toxicity:

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

Page 10 of 17

Trading name:		BIOFIX GL							
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2				

Product code:	BFC	JL-X^^	Date of c	compliation	1.	12.11.2022.	V	ersion:		2
									,	
Subchronic oral	No in availab	nformation ble	No information available	No informatio available	n	No information available	No informa availab		_	
Subchronic dermal	No in availab	oformation ble	No information available	No informatio available	n	No information available	No informa availab		_	
Subchronic inhalation	No in availab	oformation ble	No information available	No informatio available	n	No information available	No informa availab		_	
Chronic oral	No in	oformation ble	No information available	No informatio available	n	No information available	No informa availab		-	
Chronic dermal	No in availab	oformation ble	No information available	No informatio available	n	No information available	No informa availab		_	
Chronic inhalation	No in availab	oformation ble	No information available	nformation information infor		No information available	No information available		-	
	-						i			
Specific	target o	rgan toxicity	y – repeated exp	oosure (STO)	T RE)	):				
			Specific effects	_		Target orga	an		N	ote
Subacute oral		No inform	ation available	١	No information available -					
Subacute dermal		No inform	nation available No		No information available -		-			
Subacute inhalati	on	No inform	nation available		No information available		-			
Subchronic oral		No inform	nation available No		No information available -		-			
Subchronic derm	al	No inform	ation available	١	No ir	nformation available -		-		
Subchronic inhala	ation	No inform	ation available	١	No information available		-			
Chronic oral		No inform	ation available	١	No ir	nformation ava	ilable	-		
Chronic dermal		No inform	ation available	١	No ir	nformation ava	ilable	-		
Chronic inhalatio	n	No inform	ation available	Ŋ	No ir	nformation ava	ilable	-		
		cinogenicity	, mutagenicity,	<u> </u>		-				
	Carcinogenicity:					on available				
	Mutagenicity in-vitro:					on available				
Genotox						on available				
	nicity <i>in-</i> 			No information available						
Germ ce	ll mutag	enicity:		suspected of causing genetic defects						

No information available



Page 11 of 17

Trading name:		BIOFIX GL						
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2			

	Summary of evaluation of the CMR properties:
11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other informations:
	-

SECTION 12. Ecologi	cal informat	tion				
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	Fish	No information available	8.140 mg/l (ethanol) 186 – 272 mg/l (glyoxal)	-
Crustacea:	EC <sub>50</sub>	48 hours	Daphnia magna	No information available	7.800 mg/l (ethanol) 69.2 mg/l (glyoxal)	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	algae	No information available	5.000 mg/l (ethanol)	-
Other organisms:	-	-	No information available	No information available	No information available	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-



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

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

Page 12 of 17

Trading name: BIOFIX GL									
Product code	):	BFGL-X**		Date of	compilation:	12.11.2	2022.	Version:	2
Other organism	ns:	-	-	-	_		-	_	1
12.2. Persis	tence a	and degradab	ility						
		adation							
	Deg	radation half-	lives		Method		E	valuation	Note
Marine water	No in	formation ava	ailable	No inforr	nation available	)	No infor	mation availabl	e -
Fresh water	No in	formation ava	ailable	No inforr	nation available	)	No inform	mation availabl	e -
Air	No in	formation ava	ailable	No inform	mation available	•	No infor	mation availabl	e -
Soil	No in	formation ava	ailable	No inform	nation available	•	No inform	mation availabl	e -
	gradat								
% Degradatio	n	Time (days	)	<u> </u>	Method	Eva	luation	No	ote
-	-			-		-		-	
12.3. Bioac	cumula	ative potential							
		er partition co		t (loa Kov	γ)				
Value		entration	рН	°C	Method	E <sup>,</sup>	Evaluation		
_			<u>- ''</u>	_	-	_		-	Note
i		i.		<u> </u>		i		i	
Bioco	ncentr	ation factor (E	BCF)						
Value		Specie	·S		Method	Eval	uation	N	ote
No information		No informatio	n		ormation	No inforr	mation	No informa	ation
available	ā	available		availal	ole	available		available	
Cl	·ia '	havioit:							
Chror	nic eco	toxicity	Ev	nosuro					
Chror		toxicity Dose		posure time	Species	Metl	nod	Evaluation	Note
:	е	Dose		•	Species	Metl		Evaluation	Note -



Page 13 of 17

Trading name:		BIOFI	X GL		
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

Produc	ct co	de:	BFGL-X**	Date of con	npilation:	12.11.	2022.	Version	n: 2	
				available av	vailable	availab	مار	available		
Chronic		city on aphnia)	EC <sub>50</sub>	No Ninformation in		No inform availab	ation	No information - available		
12.4.	Мо	bility in so	oil							
	Knc	wn or pro	edicted distributi	on in environmen	tal comparti	ments:				
	No	informati	on available							
	Surface tension:									
		Value	°C	Concentratio	n	Method	mation		Note	
		rmation ilable	No information available	No information	n No info availab	ormation le				
	Ads	orption /	desorption							
Transpo	ort		coefficient ry's constant	log Kow	Evaporat	ion rate	М	ethod	Note	
Soil-wa	iter	No availabl	information e	No information available	n No info available		No i availabl	nformation le	-	
Water-a	air	No availabl	information e	No information available	n No info available		No i availabl	nformation le	-	
Soil-air		No availabl	information e	No information available	n No info available		No i availabl	nformation le	-	
12.5.	Res	ults of PB	T and vPvB asses	sment						
			on available							
12.6.	End	ocrine di	srupting properti	es						
	No	known er	ndocrine disrupti	ng properties that	affect the e	nvironme	ent.			
2.7.	Oth	er advers	e effects							
	No	adverse e	effects are expect	ed.						
ECTIO	N 13	. Disposa	al consideration	s						
13.1.	W	aste trea	tment methods							



Page 14 of 17

Trading name:		BIOFIX GL						
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2			

Product code: BFGL-X**		Date of compilation:	12.11.2022.	Version:	2
Product/Packaging disposal:					
Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.				ture	
Waste cod	des/waste designation	ons according to Law:			
Packaging	that contains resid	ual hazardous substances o	r is contaminated w	vith hazardous s	ubstances
Waste tre	atment – relevant in	formation:			
No inform	nation available				
1					
Sewage disposal – relevant information:					
Waste must not be disposed of into the sewage system.					
:					
Other disposal recommendations:					
the minist	ry in charge. Do not	dispose of the packaging i	nto the sewage syst	tem. Submit the	remains to
Relevant Community provisions:					
-					
1					
N 14. Transp	oort information				
		(ADR)			
ber:		1170			
er shipping	name:	Ethanol solution			
	Product/P Submit for Protection  Waste coor Packaging  Waste tree No inform  Sewage d Waste mu  Other disp Do not en the minist the collect occur.  Relevant of the collect occur.  Relevant occur.  Transporting ber:	Product/Packaging disposal: Submit for disposal to the legaritation.  Waste codes/waste designation Packaging that contains resident Waste treatment – relevant into the legaritation and the legaritation and the legaritation are sident to the legaritation and the legaritation are sident to legaritation and the legaritation are sident to legaritation and the legaritation are sident to legaritation are sident to legaritation and legaritation are sident legaritation.  Sewage disposal – relevant into legaritation are sident legaritation are sident legaritation.  Other disposal recommendation are sident legaritation.  Transport information  Transporting/shipment by road.	Product/Packaging disposal:  Submit for disposal to the legal person authorized by the Protection.  Waste codes/waste designations according to Law:  Packaging that contains residual hazardous substances of Waste treatment – relevant information:  No information available  Sewage disposal – relevant information:  Waste must not be disposed of into the sewage system.  Other disposal recommendations:  Do not empty remnants of the product into drains. Submathe ministry in charge. Do not dispose of the packaging in the collectors authorized by the ministry in charge. Do not occur.  Relevant Community provisions:	Product/Packaging disposal:  Submit for disposal to the legal person authorized by the Ministry of Enviror Protection.  Waste codes/waste designations according to Law:  Packaging that contains residual hazardous substances or is contaminated waste treatment – relevant information:  No information available  Sewage disposal – relevant information:  Waste must not be disposed of into the sewage system.  Other disposal recommendations:  Do not empty remnants of the product into drains. Submit the remains to the the ministry in charge. Do not dispose of the packaging into the sewage system cocur.  Relevant Community provisions:	Product/Packaging disposal:  Submit for disposal to the legal person authorized by the Ministry of Environmental and Nat Protection.  Waste codes/waste designations according to Law:  Packaging that contains residual hazardous substances or is contaminated with hazardous s  Waste treatment – relevant information:  No information available  Sewage disposal – relevant information:  Waste must not be disposed of into the sewage system.  Other disposal recommendations:  Do not empty remnants of the product into drains. Submit the remains to the collectors auth the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the the collectors authorized by the ministry in charge. Do not dispose of in places where ignitic occur.  Relevant Community provisions:  -  I 14. Transport information  Transporting/shipment by road (ADR)  Der: 1170

Transporting/shipment by road (ADR)		
UN number:	1170	
UN proper shipping name:	Ethanol solution	
Transport hazard class(es):	3	
Packing group:	III	
Environmental hazards:	No information available	
Special precautions for user:	-	
Transporting/shipment by	rail (RID)	
UN number:	1170	
UN proper shipping name:	Ethanol solution	
Transport hazard class(es):	3	
Packing group:	III	
Environmental hazards:	No information available	
Special precautions for user:	-	



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

Page 15 of 17

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

UN number:		1170		
UN proper shipping name:		Ethanol solution		
Transport hazard class(es):		3		
Packing group:		III		
Environmental hazards:		No information available		
Special precautions for user:		-		
Transporting/shipm	ent by sea (IM	IDG)		
UN number:		1170		
UN proper shipping name:		Ethanol solution		
Transport hazard class(es):		3		
Packing group:		III		
Environmental hazards:		No information available		
Special precautions for user:		-		
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:		-		
Transporting/shipm	ent by air (ICA	AO-TI/IATA-DGR)		
UN number:		1170		
UN proper shipping name:		Ethanol solution		
Transport hazard class(es):		3		
Packing group:		III		
Environmental hazards:		No information available		
Special precautions for user:		-		
	·			
		ovision 144 - Aqueous solution containing 24% or less alcohol volume, o classification.		
I.A.		ovision A58 - Aqueous solution containing 24% or less alcohol volume, o classification.		

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



Page 16 of 17

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;  Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;  Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;  Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;  REACH Restrictions on the manufacturing, placing on the market and use of certain
	Information according 199 guideline)	dangerous substances, mixtures and articles (Annex XVII); 09/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessmen	nt
	no information	

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:	-



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

Page 17 of 17

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	12.11.2022.	Version:	2

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)					
Classifi	Classification according to CLP		Classification procedure			
-			-			
16.5.	Rele	evant H statements (num	ber and full text)			
		225	Highly flammable liquid and vapour.			
		226	Flammable liquid and vapour.			
		315	Causes skin irritation.			
	H:	317	May cause allergic skin reaction.			
		319	Causes serious eye irritation.			
		332	Harmful if swallowed.			
		341	Suspected of causing genetic defects.			
16.6.	Trai	ning advice:	-			
	. Further information:		"X" in the product code marks different volumes (different packagings of the product)			
16.7.			We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to chemical safety assessment
-