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Trading name:	4% FORMALDEHYDE				
Product code:	F4-X**	Revision date:	06 November 2023	Version:	9

SECTI	ON 1 IDENTIFICATION	OF THE SUBS	TANCE/MIX	XTURE AND OF THE COMPANY/UNDERTAKING	
1.1	Product identifier				
	Trading name:	4% FORMA	4% FORMALDEHYDE		
	Chemical name:	-			
	Catalogue number:	F4-X**			
1.2	Relevant identified use	es of the subs	tance or mix	cture and uses advised against	
	Uses:		Fixative fo	r use in histology.	
	Uses advised against:		Only the id	dentified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplier of the safety data sheet				
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Fax no.:		+385 1 2404039		
	e-mail of competent p	erson:	msds@biognost.hr		
	National contact:	National contact:		-	
1.4	Emergency telephone	Emergency telephone number			
	National Protection ar	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:	Other information:		-	

SECTIO	SECTION 2 HAZARDS INFORMATION				
2.1	Classification of the substance or mixture				
2.1.1	Classification according to (EC) Regulation N	o. elements			
	Hazard class and category code:	Hazard statements*:			
	Acute Tox. 4	H302			
	Acute Tox. 4	H312			
	Acute Tox. 4	H332			
	Skin Sens. 1	H317			
	Muta. 2	H341			
	Carc. 1B	H350			
2.1.2.	Additional information				
	-				
*For fu	ıll text of Hazard- and EU Hazard-statements: se	ee Section 16			



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2.2	Label elements	
	Product identification:	4% FORMALDEHYDE (stabilized 10% formalin solution)
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	
	Signal word:	Danger
	Hazard statements:	 H302 Harmful if swallowed. H312 Harmful in contact with skin. H317 May cause an allergic skin reaction. H332 Harmful if inhaled. H341 Suspected of causing genetic defects. H350 May cause cancer.
	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. P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P308 + P313 IF exposed or concerned: Get medical advice/ attention.
	Further information:	-
2.3	Other hazards	
		ins no components considered to be either persistent, bioaccumulative and and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3 CO	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)		
50-00-0/ 200-001-8/ 605-001-00-5	01-2119488953-20- XXXX	4 – 5 %	formaldehyde, 37 %	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Skin Corr. 1B; H314 Skin. Sens. 1; H317 Muta. 2; H341 Carc. 1B; H350		



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67-56-1/ 200-659-6/ 603-001-00-X 01-2119433307-44- XXXX	1 – 3 %	methanol	Flam. Liq. 2; H225 Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 STOT SE 1; H370
---	---------	----------	---

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:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and ef	fects, both acute and delayed
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medi	cal attention and special treatment needed

SECTION 5 FIREFIGHTING MEASURES				
5.1	Extinguishing media			
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂		
		Large fire - water spray or alcohol-resistant foam		



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	Unsuitable extinguishing media:	No information available		
5.2	Special hazards arising from the su	Special hazards arising from the substance or mixture		
	Hazardous combustion products:	Not flammable. Surrounding fire may cause hazardous fumes to be released.		
5.3	Advice for firefighters			
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.			
5.4	Additional information			
	Do not contaminate the environment	ent with extinguishing media.		

6.1	Personal precautions, protectiv	re equipment and emergency procedures	
6.1.1.	For non-emergency personnel	<u> </u>	
	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, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.		
6.3	Methods and material for cont	ainment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.	
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.	
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).	
6.4	Reference to other sections		

SECTIO	IN / HANDLING AN STORAGE

Precautions for safe handling 7.1



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7.1.1.	Protection measures	Protection measures				
	Measures to prevent fire:		Use in well ventilated storage rooms.			
	Measures to prevent aerosol and dust generatio	n:	Secure proper ventilation.			
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.			
	Other measures:		-			
7.1.2.	Advice on general occupational hygiene:					
	Do not eat, drink or smoke in the workspace. Th	oroughly was	sh hands after work and before eating.			
7.2	Conditions for safe storage, including any incom	patibilities				
	Technical measures and storage conditions:		htly closed and upright set containers in a ated storage rooms at temperatures ranging 25 °C.			
	Packaging materials:	Manufactu containers	turer's original packaging. Avoid metal rs.			
	Requirements for storage rooms and vessels:	Keep away tightly clos	way from food and drink. Keep the containers closed.			
	Advices for storage equipment:	must be re	e must be made of hard material; floors esistant to chemicals. There must be no drain ly leads into sewage system. Secure proper .			
	Further information on storage conditions:	Do not place the unused material in the storage and do not use empty containers for storing oth chemicals. Do not store with incompatible mater (see Section 10).				
7.3	Specific end use(s)					
	Recommendations:	-				
	Industrial sector specific solutions:	-				

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION							
8.1 Control para	8.1 Control parameters						
Substance		CAS No		Occupational exposure limit values/short term values			Biological limit values
				ppm	mg/m³		
Formaldehyde		50-00-0		0.3/0.6	0.37/0.74	-	
Methanol		67-56-1		200/-	260/-	-	
Substance name:	-						
EC No:	-	CAS No:	-				



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DNEL					
		Indus	trial		
Route of	Acute	Acute	Ch	ronic	Chronic
exposure:	effect local	effect systemic	effe	ct local	effect systemic
Oral	-	-	-		-
Inhalation	0.75 mg/m ³ (formaldehyde) 130 mg/m ³ (methanol)	130 mg/m³ (methanol)	0.375 mg/n (formaldeh) 130 mg/ m		9 mg/m³ (formaldehyde) 130 mg/m³ (methanol)
Dermal	-	20 mg/kg (methanol)	0.037 mg/c (formaldeh		240 mg/kg (formaldehyde) 20 mg/kg (methanol)
Critical physical par	rameters: solubility	, flammability, corros	sivity:	-	
		Consu	umer		
Route of	Acute	Acute	Ch	ronic	Chronic
exposure:	effect local	effect systemic	effe	ct local	effect systemic
Oral	-	4 mg/kg (methanol)	-		4.1 mg/kg (formaldehyde) 4 mg/kg (methanol)
Inhalation	26 mg/m³ (methanol)	26 mg/m ³ (methanol)	0.1 mg/m ³ (formaldeh 50 mg/m ³		3.2 mg/m³ (formaldehyde) 26 mg/m³ (methanol)
Dermal	-	4 mg/kg (methanol)	0.012 mg/c (formaldeh		102 mg/kg (formaldehyde)
PNEC		(methanol)	(iormaiden	iyue)	4mg/kg (methanol)
_	taction target		PNEC		
Environmental prot	ection target		0.44 mg/l (formaldehyde) 20.8 mg/l (methanol)		
Freshwater sedime	nts		2.3 mg/kg (formaldehyde) 77 mg/kg (methanol)		
Marine water			0.44 mg/l (formaldehyde) 2.08 mg/l (methanol)		
Marine sediments			2.3 mg/kg (formaldehyde) 7.7 mg/kg (methanol)		
Food chain			No informa	ation available	
Microorganisms in	sewage treatment		0.19 mg/l (100 mg/l (r	formaldehyde) methanol)	
Soil (agricultural)				(formaldehyde (methanol))
Air			No informa	ation available	
			•		



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8.2	Exposure controls				
8.2.1.	Engineering measures				
	Substance/mixture related measurevent 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 e	xposure:	In accordance with Section 7.		
	Organisational measures to preversexposure:	ent	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent ex	xposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.		
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	levels of	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.		
8.2.2.2.	Skin protection	<u>i</u>			
	Hand protection:	Protectiv	re nitrile gloves, 0.11 mm thick (EN 374).		
	Other skin protection:		tistatic clothing made of natural fibers (such as cotton) g sleeves (EN 340) and shoes that cover the entire foot.		
8.2.2.3.	Respiratory protection:	combine	mask (EN 136) or half mask (EN 140) equipped with a d "A1 + Form" filter (EN 143) used when concentration ceed GVI.		
8.2.2.4.	Thermal hazards:	No infor	mation available		
8.2.3.	Environmental exposure controls	3			
	Substance/mixture related measures to prevent exposure:	See Secti	ion 6		
	Structural measures to prevent exposure:	Use modern equipment.			
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.			
	Technical measures to prevent exposure:	See Secti	ion 6		

SECTION	SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES				
9.1	9.1 Information on basic physical and chemical properties				
		Value	Method		
	Physical state:	liquid	No information available		



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	Colour:	colorless	No information available			
	Odour/odour threshold:	sharp/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:	cca 100 °C at 1,013 hPa	No information available			
	Flammability:	No information available	No information available			
	Lover and upper explosion limit:	No information available	No information available			
	Flash point:	Not applicable	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:	completely soluble in water	No information available			
	Partition coefficient noctanol/water (log value):	No information available	No information available			
	Vapour pressure:	No information available	No information available			
	Density and/or relative density	No information available	No information available			
	Relative vapour density:	No information available	No information available			
	Particle characteristics:	No information available	No information available			
9.2	Other information					
	4% Formaldehyde is non-flammab formalin concentration is ≤25%	4% Formaldehyde is non-flammable aqueous solution because it is stabilized using methanol and formalin concentration is ≤25%				

SECTIO	ECTION 10 STABILITY AND REACTIVITY							
10.1	Reactivity:	See subsections 10.3 through 10.5.						
10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).						
10.3	Possibility of hazardous reactions:	Acids, nitrogen oxides, hydrogen peroxide, oxidizing agents, polymerization initiators, alkaline metals.						
10.4	Conditions to avoid:	Heat sources, low temperatures.						
10.5	Incompatible materials:	Various metals, alloys, plastic, magnesium, zinc alloys.						
10.6	Hazardous decomposition products:	No information available.						

SECTION 11 TOXICOLOGICAL INFORMATION							
11.1	Information on toxicological effects						
	Acute toxicity:						



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

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rioduct code.	14-7		IXEVISION	date.	JINOVE	111061 202.	J V	reision.
Route of exposure:	Method	Species	Do	ose LD ₅₀ /LC ₅₀ or ATE _{mix}	r	Exposure ti	me	Results
Oral:	-	rat	LD ₅₀		٨	No informatio available		100 mg/kg (formaldehyde 100.1 mg/kg (methanol)
Dermal:	-	rabbit		LD ₅₀	١	No information available		270 mg/kg (formaldehyde) 300.1 mg/kg (methanol)
Inhalation:	-	rat		LC ₅₀		4 h		0.57 mg/l (formaldehyde) 3.1 mg/l (methanol)
C::::- t-		odniko nimala a		TOT CEV				
Specific ta		xicity – single e	exposure (S	Target organ				
		Specific effects						Note
Oral:		ition available		No information			-	
Dermal:		ition available		No information available				
Inhalation:	No informa	ition available		No information	on availa	-		
Aspiration	hazard:		No infor	mation availabl	e.			
Irritation a	and corrosion							
i i	Ехр	osure time	Spec	ies Evalu	ıation	Method		Note
Skin corrosion/irritation:	- •		rabbit	-		-	No	skin irritation.
Serious eye damage/irritation	-		rabbit	-		-	No	eye irritation.
Sensitizati	on							
Skin sensitization:		ay cause allergi	ic skin reac	tion.				
Respiratory sensitiz		lergic persons i						
Trespiratory sensitiz	Alon. Al	iergie persons i	may alspia	,				
Symptoms	s related to th	ne physical, che	mical and t	oxicological ch	aracteri	stics		
Oral exposure:	If ingeste		s of the mo				er of p	erforation of the
Dermal exposure:	Dependi	ng on concentr	ration and	exposure time,	redness	accompar	nied by	sensation of

stinging and pain may occur, as well as skin cracking and rash.



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Inhalation exposi	ure:		ding on concentration and exposure time, it may lead to mucosal irritations, cough, ess of breath, possible damages: damage of respiratory tract							
Eye exposure:		Depending o Risk of blind	on concentration and exposure time, it may lead to stinging, tearing, and pain. ness.							
Repeate	ed dose	e toxicity (sub	acute, subchro	onic, chronic)						
, ,		Dose	Exposure time	Species	Method	Evaluation	Note			
Subacute oral	No availa	information able	No information available	No information available	No information available	No informatio available	n -			
Subacute dermal	No availa	information able	No information available	No information available	No information available	No informatio available	n -			
Subacute inhalation	No information available		No information available	No information available	No information available	No informatio available	n -			
Subchronic oral	No availa	information able	No information available	No information available	No information available	No informatio available	n -			
Subchronic dermal	No availa	information able	No information available	No information available	No information available	No informatio available	n -			
Subchronic inhalation	No availa	information able	No information available	No information available	No information available	No informatio available	n -			
Chronic oral	No availa	information able	No information available	No information available	No information available	No informatio available	n -			
Chronic dermal	No availa	information able	No information available	No information available	No information available	No informatio available	n -			
Chronic Inhalation	No information available		No information available	No information available	No information available	No informatio available	n -			
Specific	target	organ tovicit	v - reneated a	xposure (STOT						
Specific	target	organ toxicit	Specific effec	•		rgan	Note			
Subacute oral		No informa	tion available		Target organ No information available		-			
Subacute dermal			tion available		No information		-			
Subacute inhalati			tion available		No information		-			



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Subchron	nic oral	No information available		No information available	-		
Subchron	nic dermal	No information available		No information available	-		
Subchror	nic inhalation	No information available		No information available	-		
Chronic c	oral	No information available		No information available	-		
Chronic c	ic dermal No information available			No information available	-		
Chronic i	hronic inhalation No information available			No information available	-		
	CMR effects (ca	arcinogenicity; mutagenicity; repro	ductive	toxicity)			
	Carcinogenicity	y:	Possib	le carcinogen.			
	Mutagenicity <i>ii</i>	n vitro:	No inf	ormation available			
(Genotoxicity:		No information available				
	Mutagenicity <i>ii</i>	n vivo:	No inf	ormation available			
	Germ cell muta	agenicity:	Eviden	ce of genetic defects.			
	Reproductive t	oxicity:	No inf	ormation available			
-							
	Summary of ev	valuation of the CMR properties:	No information available				
·			ż				
11.2	Information or	other hazards:					
11.2.1.	Endocrine disr	upting properties:					
	components disrupting prop 57(f) or Comm 2017/2100 or	ce/mixture does not contain considered to have endocrine perties according to REACH Article hission Delegated regulation (EU) Commission Regulation (EU) yels of 0.1% or higher.					
11.2.2.	Other informat	ions:					

SECTION 12 ECOLOGICAL INFORMATION:								
12.1 Toxicity								
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		
Fish	LC ₅₀	96 hours	fish (Morone saxatilis)	-	6.7 mg/l (formaldehyde) 15.400 mh/l (methanol)	-		



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Crustacea:		EC ₅₀	48 hours	water f (Daphr magne	nia	-	(forma 18.26	mg/l ldehyde) 50 mg/l :hanol)	-
Algae/aquatic μ	olants	IC ₅₀	4 days	green a	lgae	-	(forma 22.00	9 mg/l ldehyde) 00 mg/l :hanol)	-
Other organism	ıs	-	-	-		-	-		-
Chronic (long-t toxicity	hronic (long-term) Dose Dose		Exposur time	e Specie	es	Method	Eval	uation	Note
ish LC ₅₀		LC ₅₀	96 hours	No inform available	nation	No information available	No info	ormation le	-
Crustacea:	acea: E		48 hours	No inform available	nation	No information available	No information available		-
Algae/aquatic plants		IC ₅₀	72 hours	No inform available	nation	No information available	No information available		-
Other organisms -		-	-		-	-		-	
12.2 Persist	ence ar	nd degradak	oility						
Abiotio	degra	dation			:				
	De	gradation h	alf-lives	Method	Method Evalua		ion		Note
Marine water	No in	formation a	vailable	No information	on	No information available	on	-	
Fresh water	No in	formation a	vailable	No information	on	No information available	on	-	
Air	No in	nformation a	vailable	No information	on	No information	on	-	
Soil	No in	oformation a	vailable	No information	on	No information	on	-	
Biodeo	gradatio	on .							
% Degradation		Time (day	/s)	Method	ł	Evaluati	on		Note
No information available	No ir	nformation a	ıvailable	No informati			on	No infor	



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					•			:				
	1				- 1		·		i			
12.3	Bioaccum	ulative p	otentia	I								
	Partition c	oefficie	nt: n-oc	tanol/wat	er (log Ko	ow):						
Valu	e Co	ncentrat	tion	рН	°C	М	ethod	Eval	uation		Note	
0,021	_			_	formal	dehyde	_		_			
-0.77	-	-		-	-	methar	nol	-		-		
				1								
	Bioconcen	tration	factor (E	BCF)								
V	Value Species					Method	d	Evaluat	tion		Note	
No info	No information No information				No info	ormatic	on	No informat				
availabl	available available			availab	le		available		-			
	Chronic ed	cotoxicit	У								:	
	Value		Dos	Δ :	posure time		ecies	Method	Evaluation		Note	
Chronic	toxicity on	fich	LC ₅₀	No	No information		mation	No informatio	No informatio			
Cilionic	. toxicity on	11211	LC50		lable	availa		n available	available	ווכ	-	
Chronic	toxicity on			No		No		No	No			
	ea (<i>Daphnia</i>		EC ₅₀		rmation lable	infor	mation	informatio n available	information available	on	-	
				aval	iabie	avallo	שוטוכ	ii avallable	available			
12.4	Mobility	o soil										
14.4	Mobility in Known or		nd dictri	hution in	onviron	nontal	compart	monts:				
	No inform	-		Dution in	environin	ieritai (Jonipart	inents.				
	Surface te		/allable									
		nsion:	0.0					NA 11 1			NI I	
	Value	N 1	°C	(Concentra	ation		Method			Note	
	No informatio available		ormatio ailable	n i	o informa ailable	ntion	No inf availat	ormation ole	-			



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	Adsorption / desorption				
Transpor	t A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-wate	No information available	No information available	No information available	No information available	-
Water-ai	r 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 asses	ssment			
	This substance/mixture conta toxic (PBT), or very persistent	•		-	
12.6.	Endocrine disrupting properti	es			
	The substance/mixture does r according to REACH Article 5 Regulation (EU) 2018/605 at I	7(f) or Commission	n Delegated regulat		
12.6.	Other adverse effects				
	No information available				
SECTION	I 13 DISPOSAL CONSIDERAT	ΓIONS			
13.1	Waste treatment methods				
13.1.1.	Product/Packaging disposal	:			
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.				
13.1.2.	Waste codes/waste designations according to Law:				
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances				
13.1.3.	Waste treatment – relevant	information:			
	No information available				
13.1.4.	Sewage disposal – relevant	information:			



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	Waste must not be disposed of into the sewage system.			
13.1.5.	Other disposal recommendations:			
	authorized by the ministry in o	t's remains into the sewage system. Submit the remains to the collectors charge. Do not dispose of the packaging into the sewage system. Submit is authorized by the ministry in charge.		
13.1.6.	Relevant Community provision	ns:		
	-			
SECTION	14 TRANSPORT INFORMATION	ON		
-	Transporting/shipment by road	(ADR)		
UN numb	per:	Not applicable		
UN prope	er shipping name:	-		
Transport	t hazard class(es):	-		
Packing g	group:	-		
Environm	entally hazardous:	-		
Special p	recautions for user:	-		
-	Transporting/shipment by rail (F	RID)		
UN numb	per:	Not applicable		
UN prope	er shipping name:	-		
Transport	t hazard class(es):	-		
Packing g	group:	-		
Environm	entally hazardous:	-		
Special p	recautions for user:	-		
I	nland waterway transport (ADN			
UN numb	oer:	Not applicable		
UN prope	er shipping name:	-		
Transport	t hazard class(es):	-		
Packing g	group:	-		
Environmentally hazardous:		-		
Special precautions for user:		-		
Transporting/shipment by sea (IMDG)				
UN number:		Not applicable		
UN proper shipping name:		-		
Transport	t hazard class(es):	-		
Packing g	group:	-		



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Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	3334
UN proper shipping name:	Aviation regulated liquid, n.o.s. (formaldehyde)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	None
Special precautions for user:	no information
Formaldehyde solutions, nonflammable, containing less than 25% of formaldehyde do not adhere to the ADR regulations.	

5.1 Safety, health and enviror	nmental 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 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);



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

SECTION	ON 16	Other information			
16.1	Ind	ication of changes:	-		
16.2	Abl	previations 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.	.3. Key literature references and source of data:		-		
16.4.		ssification and procedure (2/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)		
Classif	icatio	n according to CLP	Classification procedure		
-			-		
16.5.	Rel	evant H statements (numb	er and full text)		
	H:	225	Highly flammable liquid and vapor.		
		301	Toxic if swallowed.		
		302	Harmful if swallowed.		
		311	Toxic in contact with skin.		
		312	Harmful in contact with skin.		
		314	Causes severe skin burns and eye damage		
		317	May cause allergic skin reaction.		
		331	Toxic if inhaled.		
		332	Harmful if inhaled.		
		341	Suspected of causing genetic defects.		
		350	May cause cancer.		
		370	Causes damage to organs.		



SAFETY DATA SHEET

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

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16.6.	Training advice:	-
		** "X" in the product code marks different volumes (different packagings of the product)
16.7.	Further information:	We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX:

EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT