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Trading name:	10% FORMALDEHYDE				
Product code:	F10-X**	Revision date:	25 September 2023	Version:	8

1.1	Product identifier			
	Trading name:	10% FORM	10% FORMALDEHYDE	
	Chemical name:	-		
	Catalogue number:	F10-X**		
1.2 Relevant identified uses of the substance or mixture and uses advised against		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 24	09997
	Fax no.:		+385 1 2404039	
	e-mail of competent p	person:	msds@bio	ognost.hr
	National contact:		-	
1.4	Emergency telephone	Emergency telephone number		
	National Protection a	nd Rescue Dire	ectorate:	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 according to (EC) Regulation No.	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 ful	*For full text of Hazard- and EU Hazard-statements: see Section 16				



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2.2	Label elements	
	Product identification:	10% FORMALDEHYDE (stabilized 25% formalin solution)
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	
	Signal word:	Danger
	Hazard statements:	<ul> <li>H302 Harmful if swallowed.</li> <li>H312 Harmful in contact with skin.</li> <li>H317 May cause an allergic skin reaction.</li> <li>H332 Harmful if inhaled.</li> <li>H341 Suspected of causing genetic defects.</li> <li>H350 May cause cancer.</li> </ul>
	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	
	This substance/mixture contains no components considered to be either persistent, bioaccumulat toxic (PBT), or very persistent 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	7 – 10 %	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		



### **SAFETY DATA SHEET**

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

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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
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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 symptom 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 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:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.		
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.		
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.		
4.3	Indication of any immediate medi	cal attention and special treatment needed		

SECTIO	SECTION 5 FIREFIGHTING MEASURES		
5.1	Extinguishing media		
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO <sub>2</sub>	
		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	ubstance 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 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 consistency (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	ON 7 HANDLING AN 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.	
	Measures to prevent aerosol and dust generation	on:	Secure proper ventilation.	
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.	
	Other measures:		-	
7.1.2.	Advice on general occupational hygiene:			
	Do not eat, drink or smoke in the workspace. Th	oroughly was	sh hands after work and before eating.	
7.2	Conditions for safe storage, including any incom	npatibilities		
	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	ırer's original packaging. Avoid metal	
	Requirements for storage rooms and vessels:	Keep away tightly clos	r from food and drink. Keep the containers sed.	
	Advices for storage equipment:	must be re	le 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:	and do no	t use empty containers for storing other Do not store with incompatible materials on 10).	
7.3	Specific end use(s)			
	Recommendations:	_		
	Industrial sector specific solutions:	-		

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION						
8.1 Control parameters	3.1 Control parameters					
Substance	CAS No	·	exposure limit t 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					
		Indu	strial		
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic	
Oral	-	-	-	-	
Inhalation	0.75 mg/m <sup>3</sup> (formaldehyde) 130 mg/m <sup>3</sup> (methanol)	130 mg/m <sup>3</sup> (methanol)	0.375 mg/m <sup>3</sup> (formaldehyde) 130 mg/ m <sup>3</sup> (methanol)	9 mg/m³ (formaldehyde) 130 mg/m³ (methanol)	
Dermal	-	20 mg/kg (methanol)	0.037 mg/cm <sup>2</sup> (formaldehyde)	240 mg/kg (formaldehyde) 20 mg/kg (methanol)	
Critical physical pa	rameters: solubility	, flammability, corro	sivity: -		
		Cons	umer		
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic	
Oral	-	4 mg/kg (methanol)	-	4.1 mg/kg (formaldehyde) 4 mg/kg (methanol)	
Inhalation	26 mg/m³ (methanol)	26 mg/m³ (methanol)	0.1 mg/m <sup>3</sup> (formaldehyde) 50 mg/m <sup>3</sup> (methanol)	3.2 mg/m³ (formaldehyde) 26 mg/m³ (methanol)	
Dermal	-	4 mg/kg (methanol)	0.012 mg/cm <sup>2</sup> (formaldehyde)	102 mg/kg (formaldehyde) 4mg/kg (methanol)	
PNEC					
Environmental pro	tection target		PNEC		
Fresh water			0.44 mg/l (formaldehyde) 20.8 mg/l (methanol)		
Freshwater sedime	ents		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 information available		
Microorganisms in	sewage treatment		0.19 mg/l (formaldehyde) 100 mg/l (methanol)	)	
Soil (agricultural)			0.2 mg/kg (formaldehyde 100 mg/kg (methanol)	2)	
Air			No information available		



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8.2	Exposure controls		
8.2.1.	Engineering measures		
	Substance/mixture related measure prevent exposure during identified		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 preverse exposure:	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 o	esses that stick to face (EN 166) or visor in case of lower concentration in air; protective gas mask that covers the e in case of higher levels of concentration in air.
8.2.2.2.	Skin protection		
	Hand protection:	Protective	e nitrile gloves, 0.11 mm thick (EN 374).
	Other skin protection:		istatic clothing made of natural fibers (such as cotton) sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:		mask (EN 136) or half mask (EN 140) equipped with a d "A1 + Form" filter (EN 143) used when concentration eed GVI.
8.2.2.4.	Thermal hazards:	No inforn	nation available
8.2.3.	Environmental exposure controls		
	Substance/mixture related measures to prevent exposure:	See Section	on 6
	Structural measures to prevent exposure:	Use modern equipment.  Adapt the work process to the required working conditions of the workplace.	
	Organisational measures to prevent exposure:		
	Technical measures to prevent exposure:	See Section	on 6

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES					
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
	Lower 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 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		
	10% Formaldehyde is non-flammable aqueous solution because it is stabilized using methanol and formalin concentration is ≤25%		

SECTIO	ON 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.

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



Oral exposure:

Dermal exposure:

esophagus and the stomach.

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

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Route of exposure:	Metho	d Species	Do	ose LD <sub>50</sub> /LC <sub>50</sub> ATE <sub>mix</sub>	or	Exposure tir	me	Results
Oral:	-	rat		LD <sub>50</sub>	١	lo informat available		100 mg/kg (formaldehyde) 100.1 mg/kg (methanol)
Dermal:	-	rabbit		LD <sub>50</sub>	١	No informat available		270 mg/kg (formaldehyde) 300.1 mg/kg (methanol)
Inhalation:	-	rat		LC <sub>50</sub>		4 h	0.57 mg/l (formaldehyd 3.1 mg/l (methanol	
C:ti -		And the stands	(C	TOT CEV				
Specific	target organ	toxicity – single	exposure (S		act organ			Note
Oral:	No infor	Specific effects mation available	Target organ  No information available				_	Note
Dermal:		mation available		No informati	_			
Inhalation:		mation available	No information available					
- Initialization	110	Traction available		TTO IIIIO	tion avail	4010		
Aspirati	on hazard:		No inform	mation availa	ble.			
Irritatio	n and corrosi	on						
	E	xposure time	Spec	ies Eva	luation	Method		Note
Skin corrosion/irritation	on:		rabbit	-		-	No	skin irritation.
Serious eye - damage/irritation			rabbit	-		-	No	eye irritation.
	ation							
Sensitization		May cause allerg	ic skin reac	tion.				

If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the

Depending on concentration and exposure time, redness accompanied by sensation of

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



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Inhalation exposi	IIro:			•	e time, it may lea mage of respirat		ritations, cough,		
Eye exposure:		Depending on concentration and exposure time, it may lead to stinging, tearing, and pain. Risk of blindness.							
D									
Kepeate	ed dose	Dose	acute, subchro Exposure time	Species	Method	Evaluation	Note		
Subacute oral	No availa	information able	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 availa	information able	No information available	No information available	No information available	No information available	-		
Subchronic inhalation	No availa	information able	No information available	No information available	No information available	No information available	-		
Chronic oral	No availa	information able	No information available	No information available	No information available	No information available	-		
Chronic dermal	No availa	information able	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	-		
Specific	targot	organ tovicit	v – repeated a	xposure (STOT	DE).				
Specific	target	organ toxicit	Specific effec	•	Target o	rgan	Note		
Subacute oral		No informa	tion available		No information	14010			
Subacute dermal			tion available		No information				
Subacute inhalat			tion available		No information				



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Subchro	onic oral	No information available	No information available	-			
Subchro	onic dermal	No information available	No information available	-			
Subchro	onic 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 (c	arcinogenicity; mutagenicity; repro	oductive toxicity)				
	Carcinogenicit	y:	May cause cancer.				
	Mutagenicity i	n vitro:	No information available				
	Genotoxicity:		No information available				
	Mutagenicity i	n vivo:	No information available				
	Germ cell muta	agenicity:	Suspected of causing genetic defe	cts.			
	Reproductive t	toxicity:	No information available				
	Summary of ev	valuation of the CMR properties:	No information available				
11.2	Information or	n other hazards:					
11.2.1.	Endocrine disr	upting properties:					
	components disrupting pro 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) r Commission Regulation (EU) vels of 0.1% or higher.					
	Other informa						

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



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Crustacea:		EC <sub>50</sub>	48 hours	5	water flea (Daphnia magna)	-	(forma 18.2	3 mg/l aldehyde) 60 mg/l thanol)	-
Algae/aquatic μ	olants	IC <sub>50</sub>	4 days		green algae	-	(forma 22.0	9 mg/l aldehyde) 00 mg/l thanol)	-
Other organism	าร	-	-		-	-	-		-
Chronic (long-t toxicity	erm)	Dose	Exposur time	re	Species	Method	Eva	luation	Note
Fish	ish LC <sub>50</sub>		96 hours	S	No information available	No information available	No info	ormation ble	-
Crustacea:	ustacea: E		48 hours	S	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		-
Other organisms -		-	-		-	-	-		-
	tence ai	nd degradal dation	oility						
	De	gradation h	alf-lives		Method	Evaluation		Note	
Marine water	No ir	nformation a	available		information ailable	No information available		-	
Fresh water	No in	nformation a	available		information ailable	No information available		-	
Air	No in	nformation a	available		information ailable	No information	on -		
Soil	No in	nformation a	available		o information ailable	No information	on	-	
Riode	gradatio	on.							
% Degradation	gradatio	Time (da	ys)		Method	Evaluati	on		Note
No information available	No ir	nformation a	available		o information ailable	No information	on	No infor	



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		•			3			:				1
	1				i		i		:			
12.3	Bioaccum	ulative p	otential									
	Partition c	oefficie	nt: n-oct	anol/wate	er (log Ko	ow):						
Valu	e Co	Concentration pH		°C	Me	ethod	Eval	uation		Note		
0,021	-		-	_	_	formal	dehyde	-		-		
-0.77	-		-	-	-	methar	nol	-		-		
				-	·					•		
	Bioconcen	tration	factor (B	CF)								
V	Value Species				N	Method	d	Evaluat	tion		Note	
No info	No information No information				No info	ormatic	on	No informat	tion			
availabl	vailable available		availab	available		available		-				
	Chronic ed	cotoxicit	:y	2				:	:		:	
	Value		Dose		oosure Species		ecies	Method	d Evaluat		Note	
				No				No	No			
Chronic	toxicity on	fish	LC <sub>50</sub>	1	rmation lable	information available		informatio informa n available availabl			n -	
				No		No		No	No			
	toxicity on ea ( <i>Daphnia</i>	ı)	EC <sub>50</sub>				mation	informatio	informat	ion	-	
Ciustaci	еа (Бирппи	)		avail	lable	availa	able	n available	available	•		
12.4	Mobility in	n soil										
	Known or	predicte	ed distrib	oution in	environm	nental c	compart	ments:				
	No inform	ation av	/ailable									
	Surface te	nsion:										
	Value		°C	C	Concentra	ition		Method			Note	
	No	No		No	o informa	tion	No inf	ormation				
	information available		ormation ailable	n i	ailable		availab		_			
	avallable	av	uliabic									
	<u> </u>											



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	dsorption / desorption				:
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-
12.5. R	esults of PBT and vPvB asse	ssment			
	his substance/mixture conta oxic (PBT), or very persistent	•		•	
12.6. E	ndocrine disrupting propert	ies			
a	he substance/mixture does ccording to REACH Article 5 egulation (EU) 2018/605 at	7(f) or Commission	n Delegated regulat		
			<u> </u>		
	ther adverse effects		<u> </u>		
12.6. C	other adverse effects  lo information available		<b>J</b>		
12.6. C		TIONS			
12.6. C	o information available	TIONS			
12.6. C N SECTION 13.1	lo information available  13 DISPOSAL CONSIDERA				
12.6. C N SECTION 13.1	o information available  13 DISPOSAL CONSIDERA  Waste treatment methods	l:		y of Environmental	and Nature
12.6. C N SECTION 13.1	13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposa Submit for disposal to the l	l: egal person autho	rized by the Ministr	y of Environmental	and Nature
12.6. C N SECTION 13.1	13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposa Submit for disposal to the I Protection.	l: egal person autho ations according to	rized by the Ministr		
12.6. C N SECTION 13.1.1.	13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposa Submit for disposal to the I Protection. Waste codes/waste designa	l: egal person autho ations according to idual hazardous si	rized by the Ministr		
12.6. C	13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposal Submit for disposal to the I Protection. Waste codes/waste designal Packaging that contains res	l: egal person autho ations according to idual hazardous si	rized by the Ministr		



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	Waste must not be dispo	osed of into the sewage system.	
13.1.5.	Other disposal recomme	ndations	
13.1.3.	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.		
13.1.6.	Relevant Community pro	ovisions:	
	-		
SECTIO	N 14 TRANSPORT INFORM	MATION	
	Transporting/shipment by	road (ADR)	
UN num	ber:	Not applicable	
UN prop	per shipping name:	-	
Transpo	rt hazard class(es):	-	
Packing	group:	-	
Environi	mentally hazardous:	-	
Special	orecautions for user:	-	
	Transporting/shipment by	rail (RID)	
UN num	ber:	Not applicable	
UN prop	per shipping name:	-	
Transpo	rt hazard class(es):	-	
Packing	group:	-	
Environi	mentally hazardous:	-	
Special	orecautions for user:	-	
	Inland waterway transport	(ADN)	
UN num	lber:	Not applicable	
UN prop	per shipping name:	-	
Transpo	rt hazard class(es):	-	
Packing	group:	-	
Environmentally hazardous:		-	
Special	orecautions for user:	-	
	Transporting/shipment by	sea (IMDG)	
UN number:		Not applicable	
UN prop	per shipping name:	-	
Transpo	rt hazard class(es):	-	
Packing 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:	Ш		
Environmentally hazardous:	None		
Special precautions for user:	no information		
L FIITTNAT INTORMATION:	Further information: Formaldehyde solutions, nonflammable, containing less than 25% of formaldehyde do not adhere to the ADR regulations.		

5.1 Safety, health and enviror	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 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	

SECTIO	ON 16	Other information	
16.1	Ind	ication of changes:	-
16.2	Abl	oreviations 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.		ssification and procedure u 2/2/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)
Classifi	icatior	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.

Λ	N	N	LV.	

**EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT**