

Page 1 of 19

Trading name:	BIOFORM S				
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

1.1.	Product identifier			nd of the company/undertaking	
	Trading name:	BIOFORM :	S		
	Chemical name:	-			
	Catalogue number:	BIOS-OT-X	**		
1.2.	Relevant identified use	es of the subs	of the substance or mixture and uses advised against		
	Uses:		Modified S methanol.	Schaeffer buffered fixative solution of formaldehyde in	
	Uses advised against:		Only the id	dentified uses are advised.	
	Reason why uses advis	rised against: medical device, registered at the Agency for Med		ct is intended for use only as an <i>in vitro</i> diagnostic evice, registered at the Agency for Medicinal Products and evices and there is no reason to use it for other purposes.	
1.3.	Details of the supplier	Details of the supplier of the safety data sheet			
	Supplier:	В	BioGnost Ltd.		
	Address:	N	Medjugorska 59, Zagreb		
	Telephone number:	+	+385 1 2409997		
	Fax no.:	+	+385 1 2404039		
	e-mail of competent p	erson: <u>m</u>	msds@biognost.hr		
	National contact:	-			
1.4.	Emergency telephone	number			
	National Protection an	nd Rescue Dir	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards identification					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification according to Regulation (EC) No 127	72/2008 (CLP)				
	Hazard class and category code:	Hazard statements*:				
	Flam. Liq. 2	H225				
	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				
	STOT SE 1	H370				



Page 2 of 19

Trading name:	BIOFORM S				
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

2.1.2.	Additional information					
	Endocrine Disrupting Pr	roperties:				
	No known endocrine disr	No known endocrine disrupting properties				
	Results of PBT and vPvB assessment : According to the results of its assessment, this substance i					
	PBT or a vPvB.					
*For fu	ıll text of Hazard- and EU Ha	azard-statements: see Section 16				
2.2.	Label elements					
	Product identification:	BIOFORM S				
	Identification number:	-				
	Authorization no.:	-				
	Hazard pictograms:	GHS05 GHS08				
	Signal word:	Danger				
	Hazard statements:	 H225 Highly flammable liquid and vapor. H301 + H311 + H331 Toxic if swallowed, in contact with skin or if inhaled. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H341 Suspected of causing genetic defects. H350 May cause cancer. H370 Causes damage to organs. 				



Page 3 of 19

Trading name:	BIOFORM S				
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

	Precautionary statements:	P210 Keep away from heat, hot surfaces, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P301+P330+P331 IF SWALLOWED: rinse mouth. DO NOT induce vomiting. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/attention.
	Further information:	-
2.3.	Other hazards	
	-	

SECTION 3. Co	SECTION 3. Composition/information on ingredients					
CAS/ EC/ Index no.	REACH Registration No	Mass %	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	30 - 35%	formaldehyde, 37%	Acute Tox. 3; H301 Acute Tox. 3; H311 Skin. Corr. 1B; H314 Skin. Sens. 1; H317 Acute Tox. 3; H331 Muta. 2; H341 Carc. 1B; H350		
67-56-1/ 200-659-6/ 603-001-00-X	01-21194333307- 44-XXXX	60 – 65 %	Methanol	Flam. Liq. 2; H225 Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 STOT SE 1; H370		

SECTIO	SECTION 4. First aid measures				
4.1.	Description of first aid measures				
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.			
	Following inhalation:	Remove person to fresh air. If breathing stops, immediately apply artificial respiration. If breathing difficulties occur, use emergency breathing apparatus. If the symptoms persist, immediately consult a physician.			



Page 4 of 19

Trading name:	BIOFORM S				
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

	Following skin contact:	Take off immediately all contaminated clothing. Immediately wash with plenty of water and soap 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 10 minutes. If the symptoms remain, immediately call in ophthalmologist.		
	Following ingestion:	Rinse the oral cavity, drink at most 1-2 glasses of water. Do not induce vomiting. 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 ai	der: -		
4.2.	Most important symptoms and effects, both acute and delayed			
	Following inhalation:	Irritation of the mucous membrane of the nose/throat may occur (burning sensation, urge to sneeze, and runny nose). High concentration may cause difficult breathing, coughing fits, chest tightness, headache, vertigo and drowsiness.		
	Following skin contact:	Irritation, redness with stinging and pain, skin cracking, rash, swelling, burns, blisters and delayed onset of inflammatory processes may occur.		
	Following eye contact:	Depending on concentration and exposure time, mucosa stinging, lacrimation, redness and pain may occur, as well as bleeding, delayed onset of inflammatory processes and permanent eyesight damage.		
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting (possibly of bloody content).		
4.3.	Indication of any immediate	medical attention and special treatment needed		
	-			

SECTIO	SECTION 5 Firefighting measures					
5.1.	Extinguishing media					
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO_2 Large fire - water spray or alcohol-resistant foam				
	Unsuitable extinguishing media:	No information available				
5.2.	Special hazards arising from the substance or mixture					
	Hazardous combustion products:	Possible liberation of toxic carbon monoxide and formaldehyde gases due to thermal decomposition (increased temperature). Explosive mixtures of formaldehyde vapors and air, and methanol and air also present danger.				
5.3.	Advice for firefighters					
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray, in order to prevent explosion.					



Page 5 of 19

Trading name:	BIOFORM S					
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4	

5.4.	Additional information
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.

SECTIO	ON 6. Accidental release	measure	es ·		
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency pe	rsonnel			
	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. Remove all sources of sparks and ignition. Do not smoke.		
	Emergency procedures	•	Mark the area using proper signs.		
6.1.2.	For emergency respond	ders:			
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).				
6.2.	Environmental precauti	ons:			
	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 contai	nment and cleaning up		
6.3.1.	For creating barriers, covering and sealing:	Sand or	clay barriers.		
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.			
6.3.3.	Other information:	Do not	use tools that may cause sparks.		
6.4.	Reference to other sect	ions			
	See Section 7 for inforr	nation ab	out secure handling.		
			out personal protective equipment.		
	See Section 13 for info	rmation a	bout containment.		

SECTIO	N 7. Handling and storage	
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition. Carry out measures for preventing static electricity.



Page 6 of 19

Trading name:	BIOFORM S					
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4	

	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 wash hands after work and before eating.		
7.2.	Conditions for safe storage, including any incon	npatibilities		
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C.		
	Packaging materials:	Manufacturer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.		
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.		
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).		
7.3.	Specific end use(s)			
	Recommendations:	-		
	Industrial sector specific solutions:	-		

SECTION 8. Ex	SECTION 8. Exposure controls/personal protection							
8.1. Conti	ontrol parameters							
Substance		CAS No	•	nal exposure limit ort 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/-	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*), end-of-shift urinary excretion			
* For all results consideration	s pertaining cre	atinine levels, cre	eatinine concent	ration < 0.5 g/l and	d > 3.0 g/l may not be taken into			
Substance name:								
EC No:	-	CAS No:	-					



Page 7 of 19

Trading name:	BIOFORM S					
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4	

DNEL	DNEL							
		Ind	lustrial					
Route of exposure:	Acute	Acut	e	Chronic	Chronic			
Route of exposure.	effect local	effect sys	temic	effect local	effect systemic			
Oral	-	-		-	-			
Inhalation	0.75 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)	260 mg/m³ (methanol)		0.375 mg/m³ (formaldehyde) 260 mg/m³ (methanol)	9 mg/m³ (formaldehyde) 260 mg/m³ (methanol)			
Dermal	-	40 mg/kg (m	ethanol)	0.037 mg/cm ² (formaldehyde)	240 mg/kg (formaldehyde) 40 mg/kg (methanol)			
Critical physical parar	neters: solubility, fla	mmability, cor	rosivity:	-				
		Cor	nsumer					
Route of exposure:	Acute effect local	Acute al effect systemic		Chronic effect local	Chronic effect systemic			
Oral	-	8 mg/kg (methanol)		-	4.1 mg/kg (formaldehyde) 8 mg/kg (methanol)			
Inhalation	50 mg/m³ (methanol)	50 mg/m³ (methanol)		0.1 mg/m ³ (formaldehyde) 50 mg/m ³ (methanol)	3.2 mg/m ³ (formaldehyde) 50 mg/m ³ (methanol)			
Dermal	-	8 mg/kg (me	thanol)	0.012 mg/cm ² (formaldehyde)	120 mg/kg (formaldehyde) 8 mg/kg (methanol)			
PNEC								
Environmental protec	tion target		PNEC					
Fresh water			0.44 mg/l (formaldehyde) 154 mg/l (methanol)					
Freshwater sediments			2.3mg/kg (formaldehyde) 570.4 mg/kg (methanol)					
Marine water			0.44 mg/l (formaldehyde) 15.4 mg/l (methanol)					
Marine sediments			2.3 mg/kg (formaldehyde)					
Food chain			No information available					
Microorganisms in se	wage treatment		_	/l (formaldehyde) l (methanol)				



Page 8 of 19

Trading name:	BIOFORM S					
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4	

Soil (agric	ultural)		0.2 mg/kg (formaldehyde)	
•			23.5 mg/kg (methanol)	
Air			No information available	
8.2.	Exposure controls			
8.2.1.	Appropriate engineering controls			
0.2.1.	Appropriate engineering controls		Use the product in well ventilated rooms. Use personal	
	Substance/mixture related measure prevent exposure during identified		protective equipment. Do not eat, drink or smoke in the workspace.	
	Structural measures to prevent ex	xposure:	No information available	
	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.	
	Technical measures to prevent ex	rposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.	
8.2.2.	Personal protection equipment			
8.2.2.1.	Eye and face protection:	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			
	Hand protection:	Protective gloves must be according to the Directive 89/686/E and standard EN 374. Full contact: Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min Splash contact: Gloves material: polychloroprene Glove thickness: 0.65 mm		
	Other skin protection:		Time until perforation: >240 min rotective suit with long sleeves (EN 340) that protects from als and shoes that cover the entire foot.	
8.2.2.3.	Respiratory protection:	recomm	e mask (EN 136) or half mask (EN 140) equipped with a nended "ABEK" (EN 14387) filter used when concentration sceed GVI.	
8.2.2.4.	Thermal hazards:	No info	rmation available	
8.2.3.	Environmental exposure controls			
	Substance/mixture related measures to prevent exposure:	See Sec	tion 6	
	Structural measures to prevent exposure:	Use mo	dern equipment.	



exposure:

Technical measures to prevent

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

Page 9 of 19

Trading name:	BIOFORM S					
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4	
Orc	anisational measures to	Adapt the work r	process to the rea	uired workina co	onditions of the	
nrevent exposure.		Adapt the work process to the required working conditions of the				

See Section 6

ļ	Information on basic physical and chemical properties				
		Value	Method		
	Physical state:	liquid	No information available		
	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:	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:	21°C	No information available		
	Auto-ignition temperature:	No information available	No information available		
	Decomposition temperature:	No information available	No information available		
	pH:	7.1 – 7.5	No information available		
	Kinematic viscosity:	No information available	No information available		
	Solubility:	No information available	No information available		
	Partition coefficient n- octanol/water (log value):	No information available	No information available		
	Vapour pressure:	No information available	No information available		
	Density and/or relative density	No information available	No information available		
	Relative vapour density:	No information available	No information available		
	Particle characteristics:	No information available	No information available		

SECTIO	SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	See subsections 10.3 through 10.5.	
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).	



Page 10 of 19

Trading name:	BIOFORM S				
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

10.3.	Possibility of hazardous reactions:	Explosion hazard when in contact with: nitric acid, hydrogen peroxide, nitromethane, acids, phenol, nitrogen dioxide Exothermic reactions occur with the following substances: bases, nitrides, polymerization initiators, sodium hydroxide, potassium permanganate, furfuryl alcohol, highly oxidizing agents, perchloric acid with aniline, hydrochloric acid, magnesium carbonate.
10.4.	Conditions to avoid:	Sources of heat, sparks, ignition, and low temperature.
10.5.	Incompatible materials:	Highly oxidizing agents, acids, bases and different metals, steel manufactured by melting, copper.
10.6.	Hazardous decomposition products:	Carbon oxides.

11.1. Information	on on toxicological	effects				
Acute toxi	city:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results	
Oral exposure:	No information available	rat	LD ₅₀	No information available	>200 mg/kg (formaldehyde) 125.13 mg/kg (methanol)	
Dermal:	No information available	rabbit	LD ₅₀	No information available	>270 mg/kg (formaldehyde) 375.13 mg/kg (methanol	
Inhalation exposure:	No information available	rat	LC ₅₀	4 h	0.58 mg/l (formaldehyde) 3.88 mg/kg (methanol)	
Specific ta	rget organ toxicity	– single expo	sure (STOT SE):	1		
		Specific effect	:S	Target organ	Note	
						
Oral exposure:	No information	available		-	-	
Oral exposure: Dermal exposure:	No information No information			-	-	
		available			-	
Dermal exposure:	No information	available		-	-	
Dermal exposure:	No information	available available	ossible respirator	-	-	
Dermal exposure: Inhalation exposure: Aspiration	No information	available available	ossible respirator	-	-	



Page 11 of 19

						Pag	e 11 of 19		
Trading name:				BIO	FORM S				
Product code:	BIOS	-OT-X**	Rev	vision date:	22 Dec 2022	Version:	4		
Skin corrosion/irr	ritation	No info	rmation availab	ıle -	-	-	Causes skin irritation.		
Serious irritation	to eyes:	No info	rmation availab	lle -	-	-	Causes serious eye irritation.		
Sensitiza	ation								
Dermal exposure	: May	cause aller	gic skin reactio	n.					
Inhalation exposure:	Aller	gic person	s may display ir	ritation.					
Sympto	ms related	d to the ph	nysical, chemica	al and toxicolo	gical characteristi	CS			
Oral exposure:		swallowed omach per		vere burns to 1	mouth and throat	t, and danger o	f esophagus and		
Dermal exposure	•			n concentration and exposure time, redness accompanied by sensation of pain may occur, as well as burns and blistering.					
Inhalation exposu	ure: an		on concentration and exposure time, it may lead to mucosa irritation, cough, ss of breath. Inhalation may cause formation of oedema in respiratory tract use damage.						
Eye exposure:		uses serio zard.	us eye damage	. Fumes may c	ause lacrimal irrit	ation (tearing),	blindness		
Repeate	d dose to	oxicity (sub	acute, subchro	nic, chronic)					
	D	ose	Exposure time	Species	Method	Evaluation	Note		
Subacute oral	No inf availabl	ormation e	No information available	No information available	No information available	No information available	No information available		
Subacute dermal	No inf availabl	ormation e	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 inf availabl	ormation e	No information available	No information available	No information available	No information available	No information available		
Subchronic dermal	No inf availabl	ormation e	No information available	No information available	No information available	No information available	No information available		



Page 12 of 19

Trading name:	BIOFORM S				
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

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

Specifi	c target organ toxicity – repeated exposure	e (STOT RE):	
	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	No information available
Subacute dermal	No information available	No information available	No information available
Subacute inhalation	No information available	No information available	No information available
Subchronic oral	No information available	No information available	No information available
Subchronic dermal	No information available	No information available	No information available
Subchronic inhalation	No information available	No information available	No information available
Chronic oral	No information available	No information available	No information available
Chronic dermal	No information available	No information available	No information available
Chronic inhalation	No information available	No information available	No information available

CMD effects (sousing a sousisity a post		
CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)		
Carcinogenicity:	Based on IARC tests conducted on rats, tumors appeared in nose and in pharynx. Other organisms do not yield positive results. If the operator adheres to the personal hygiene rules and uses personal protection listed in the exposure scenario, those hazards are non-existent.	
Mutagenicity in vitro:	No information available.	



Page 13 of 19

Trading name:	BIOFORM S				
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

	Genotoxicity:	No information available.
	Mutagenicity in vivo:	No information available.
	Germ cell mutagenicity:	No information available.
	Reproductive toxicity:	No information available.
	Summary of evaluation of the CMR properties:	No information available.
11.2.	Information on other hazards:	
11.2.1.	Endocrine disrupting properties:	
	No known endocrine disrupting properties that affect human health.	5
11.2.2.	Other informations:	
	-	

SECTIO	N 12. Ecologi	cal informa	tion				
12.1.	Toxicity						
Acute (toxicity	short-term)	Dose	Exposure time	Species	Method	Evaluation	Note
Fish		LC ₅₀	96 hours	Pimephales promelas	-	29.400 mg/l (methanol) 24.1 – 41 mg/l (formaldehyde)	-
Crustacea:		EC ₅₀	48 hours	water flea (Daphnia magna)	-	46.800 mg/l (methanol) 2 mg/l (formaldehyde)	-
Algae/a	aquatic plants	IC ₅₀	72 hours	algae	-	2. 5 mg/l (formaldehyde)	-
Other o	organisms	-	-	-	-	-	-
Chronic toxicity	c (long-term)	Dose	Exposure time	Species	Method	Evaluation	Note
Fish		LC ₅₀	96 hours	-	-	No information available	-
Crustac	cea:	EC ₅₀	48 hours	-	-	No information available	_
Algae/a	aquatic plants	IC ₅₀	72 hours	-	-	No information available	_
Other organisms		_	-	-	-	No information available	_
12.2.	12.2. Persistence and degradability Abiotic degradation						
		radation hal	f-lives	Method		Evaluation	Note



Page 14 of 19

Trading nam Product code	e:									
Product code					BIO	FORI	M S			
	e: BIOS	-OT-X**		Re	vision date:	22	Dec 202	2 Versio	on:	4
Marine water		ation availa			ormation avail			rmation ava		-
Fresh water	No inform	ation availa	ble	No inf	ormation avail	able	No info	rmation ava	ailable	-
Air	No inform	ation availa	ble	No inf	ormation avail	able	No info	rmation ava	ailable	-
Soil	No inform	ation availa	ble	No inf	ormation avail	able	No info	rmation ava	ailable	-
1	gradation									
% Degradatio		Time (days)			Method		Evaluati			Note
No informatio	n No info	rmation av	ailable		nformation		informati	on -	-	
available				availa	able	avaı	lable			
				1		1		***		
12.3. Bioac	cumulative	potential								
Partit	ion coefficie	nt: n-octan	ol/wate	er (log l	Kow):					
Value	Concentr	ation	ρΗ	°C	Method		Eva	luation		Note
No information available	No inform available	lo information - vailable		- No information available		on	No information - available		-	
Bioco	ncentration	factor (BCF	······································							
Value		Species		Method			Evaluation			Note
No informatio available	n No in availa	formation ble		No in availa	formation able		o informa vailable	ition	-	
Chror	nic ecotoxici	ty								
			posure Species		ı	Method	Evaluatio	on	Note	
Chronic toxicity on fish		LC ₅₀	No infor n avail	matio able	No information available	or	formati	No information available	on -	
Chronic toxicity on crustacea (Daphnia)		EC ₅₀	No infor n avail	matio	No information available	or	formati	No information available	on _	



Page 15 of 19

Trading name:	BIOFORM S						
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4		

12.4.	Mobility in soil								
	Known or predicted distribution in environmental compartments:								
	Surf	face tensic	on:			T			
		Value	°C	Concentratio		Metho			Note
		rmation ilable	No information available	No information available		No information available		-	
	Ads	orption /	desorption	:			:		
Transpo	ort		coefficient /'s constant	log Kow	E۱	aporation rate	Meth	od Note	
Soil-wa	ter	No infor available		No information available		o information railable	No inform available	nation	-
Water-a	air	No infor available		No information available			No information available		-
Soil-air		No infor available		No information available	ation No information available		No information available		-
12.5.			Γ and vPvB asse	ssment					
	No	informatio	on available						
12.6.			rupting propert					. ,	
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.								
		-	<u> </u>						
12.7.	Other adverse effects								
	No information available								
SECTIO	N 13	. Disposa	l consideration	ıs					
13.1.	W	aste treat	ment methods						
13.1.1.	Pr	oduct/Pac	ckaging disposa	ıl:					



Page 16 of 19

Trading name:	BIOFORM S					
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4	

	Protection.	ne legal person authorized by the Ministry of Environmental and Nature			
13.1.2.	Waste codes/waste desi	gnations according to Law:			
	15 01 10*: packaging the substances	at contains residual hazardous substances or is contaminated with hazardous			
13.1.3.	Waste treatment – relev	ant information:			
	No information available				
13.1.4.	Sewage disposal – releva	ant information:			
		osed of into the sewage system.			
13.1.5.	Other disposal recomme	endations:			
	authorized by the minist	roduct's remains into the sewage system. Submit the remains to the collectors cry in charge. Do not dispose of the packaging into the sewage system. Submit lectors authorized by the ministry in charge.			
13.1.6.	Relevant Community provisions:				
	Act on Sustainable Wast	e Management.			
CECTIO	N 4.4 Turner and information				
SECTIO	N 14. Transport informati				
UN num	Transporting/shipment by	3286			
	per shipping name:	Flammable liquid, toxic, corrosive n.o.s. (methanol, formaldehyde)			
	ort hazard class(es):	3 (6.1, 8)			
Packing	. ,				
	mentally hazardous:	no			
Special precautions for user:					
	Transporting/shipment by	rail (RID)			
Special	Transporting/shipment by	rail (RID) 3286			
Special UN num					
Special UN num UN prop	nber:	3286			
Special UN num UN prop	nber: per shipping name: ort hazard class(es):	3286 Flammable liquid, toxic, corrosive n.o.s. (methanol, formaldehyde)			
UN num UN prop Transpo Packing	nber: per shipping name: ort hazard class(es):	3286 Flammable liquid, toxic, corrosive n.o.s. (methanol, formaldehyde) 3 (6.1, 8)			



Page 17 of 19

Trading name:		BIOI	ORM S	•	
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

UN number:	3286
UN proper shipping name:	Flammable liquid, toxic, corrosive n.o.s. (methanol, formaldehyde)
Transport hazard class(es):	3 (6.1, 8)
Packing group:	II
Environmentally hazardous:	no
Special precautions for user:	-
Transporting/shipment by sea (II	MDG)
UN number:	3286
UN proper shipping name:	Flammable liquid, toxic, corrosive n.o.s. (methanol, formaldehyde)
Transport hazard class(es):	3 (6.1, 8)
Packing group:	II
Environmentally hazardous:	no
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:	3286
UN proper shipping name:	Flammable liquid, toxic, corrosive n.o.s. (methanol, formaldehyde)
Transport hazard class(es):	3 (6.1, 8)
Packing group:	II
Environmentally hazardous:	no
Special precautions for user:	-

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



Page 18 of 19

Trading name:		•			
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

2.	Chemical safety assessme	ent			
	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			
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)				
		Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives			
		EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;			
		EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;			
	Other EU regulations:	EC Regulation No. 2037/200 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;			
		The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);			
		EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;			

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



Page 19 of 19

Trading name:	BIOFORM S				
Product code:	BIOS-OT-X**	Revision date:	22 Dec 2022	Version:	4

Classification according to CLP		n according to CLP	Classification procedure		
_			-		
16.5.	Relevant H statements (number and full text)				
		H225	Highly flammable liquid and vapor.		
		H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.		
		H314	Causes severe skin burns and eye damage		
	H:	H317	May cause allergic skin reaction.		
		H341	Suspected of causing genetic defects.		
		H350	May cause cancer.		
		H370	Causes damage to organs.		
16.6.	Training advice:		-		
			"X" in the product code marks different volumes (different packagings of the product)		
16.7.	Fur	ther 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
-