

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

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1.	Product identifier	
	Trading name:	BIOFORM S
	Chemical name:	-
	Catalogue number:	BIOS-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Modified Schaeffer buffered fixative solution of formaldehyde in methanol.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3.	Details of the supplier 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 person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification

2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	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

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

2.1.2. Additional information





Endocrine Disrupting Properties:

No known endocrine disrupting properties

Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.

*For full text of Hazard- and EU Hazard-statements: see Section 16

2.2. Label elements

Product identification:	BIOFORM S
Identification number:	-
Authorization no.:	-
Hazard pictograms:	   
Signal word:	Danger
Hazard statements:	<p>H225 Highly flammable liquid and vapor.</p> <p>H301 + H311 + H331 Toxic if swallowed, in contact with skin or if inhaled.</p> <p>H314 Causes severe skin burns and eye damage.</p> <p>H317 May cause an allergic skin reaction.</p> <p>H341 Suspected of causing genetic defects.</p> <p>H350 May cause cancer.</p> <p>H370 Causes damage to organs.</p>

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

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

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

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.

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 aider:	-

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

-	
---	--

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.
--

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.

SECTION 6. Accidental release measures	
6.1.	Personal precautions, protective equipment and emergency procedures
6.1.1.	For non-emergency personnel
	Protective equipment: Use personal protective equipment (see Section 8).
	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 responders:
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).
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 containment 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 sections
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.

SECTION 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.

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

	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	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. Exposure controls/personal protection

8.1.	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
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 pertaining creatinine levels, creatinine concentration < 0.5 g/l and > 3.0 g/l may not be taken into consideration				
Substance name:	-			
EC No:	-	CAS No:	-	

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

DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	0.75 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)	260 mg/m ³ (methanol)	0.375 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)	9 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)
Dermal	-	40 mg/kg (methanol)	0.037 mg/cm ² (formaldehyde)	240 mg/kg (formaldehyde) 40 mg/kg (methanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute 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/m ³ (methanol)	50 mg/m ³ (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 (methanol)	0.012 mg/cm ² (formaldehyde)	120 mg/kg (formaldehyde) 8 mg/kg (methanol)
PNEC				
Environmental protection 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 sewage treatment		0.19 mg/l (formaldehyde) 100 mg/l (methanol)		

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

Soil (agricultural)	0.2 mg/kg (formaldehyde) 23.5 mg/kg (methanol)
Air	No information available

8.2.	Exposure controls
------	-------------------

8.2.1.	Appropriate engineering controls
--------	----------------------------------

	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	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:	<p>Protective gloves must be according to the Directive 89/686/EEC and standard EN 374.</p> <p>Full contact:</p> <p style="padding-left: 20px;">Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min</p> <p>Splash contact:</p> <p style="padding-left: 20px;">Gloves material: polychloroprene Glove thickness: 0.65 mm Time until perforation: >240 min</p>
--	------------------	--

	Other skin protection:	Wear protective suit with long sleeves (EN 340) that protects from chemicals and shoes that cover the entire foot.
--	------------------------	--

8.2.2.3.	Respiratory protection:	Full face mask (EN 136) or half mask (EN 140) equipped with a recommended "ABEK" (EN 14387) filter used when concentration levels exceed GVI.
----------	-------------------------	---

8.2.2.4.	Thermal hazards:	No information available
----------	------------------	--------------------------

8.2.3.	Environmental exposure controls
--------	---------------------------------

	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.

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

Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties

9.1. 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
Lower 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

9.2. Other information

-

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).

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.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity:

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 target organ toxicity – single exposure (STOT SE):

	Specific effects	Target organ	Note
Oral exposure:	No information available	-	-
Dermal exposure:	No information available	-	-
Inhalation exposure:	No information available	-	-

Aspiration hazard: possible respiratory system irritation.

Irritation and corrosion

Exposure time	Species	Evaluation	Method	Note
---------------	---------	------------	--------	------

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

Specific target organ toxicity – repeated exposure (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

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 <i>in vitro</i> :	No information available.

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

Genotoxicity:	No information available.
Mutagenicity <i>in vivo</i> :	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.	
11.2.2. Other information:	
-	

SECTION 12. Ecological information						
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	<i>Pimephales promelas</i>	-	29.400 mg/l (methanol) 24.1 – 41 mg/l (formaldehyde)	-
Crustacea:	EC ₅₀	48 hours	water flea (<i>Daphnia magna</i>)	-	46.800 mg/l (methanol) 2 mg/l (formaldehyde)	-
Algae/aquatic plants	IC ₅₀	72 hours	algae	-	2. 5 mg/l (formaldehyde)	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	No information available	-
Crustacea:	EC ₅₀	48 hours	-	-	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	-	-	No information available	-
Other organisms	-	-	-	-	No information available	-
12.2. Persistence and degradability						
Abiotic degradation						
	Degradation half-lives		Method		Evaluation	Note

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

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

Biodegradation

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

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	pH	°C	Method	Evaluation	Note
No information available	No information available	-	-	No information available	No information available	-

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

Chronic ecotoxicity

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	-

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:					
Surface tension:					
	Value	°C	Concentration	Method	Note
	No information available	No information available	No information available	No information available	-
Adsorption / 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. Results of PBT and vPvB assessment					
No information available					
12.6. Endocrine disrupting properties					
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.					
12.7. Other adverse effects					
No information available					
SECTION 13. Disposal considerations					
13.1. Waste treatment methods					
13.1.1. Product/Packaging disposal:					

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

	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:
	15 01 10*: 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:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	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 provisions:
	Act on Sustainable Waste Management.

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
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 rail (RID)
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:	None
Special precautions for user:	-
	Inland waterway transport (ADN)

Trading name:	BIOFORM 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 (IMDG)

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 (ICAO-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:	-

Further information:	-
----------------------	---

SECTION 15. Regulatory information

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

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

Other EU regulations:	<p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>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);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</p>
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
National legislation:	<p>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</p>
15.2.	Chemical safety assessment
	-

SECTION 16 Other information	
16.1.	Indication of changes: -
16.2.	<p>Abbreviations and acronyms:</p> <p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
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)

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

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

ANNEX: Exposure scenario resulting to Chemical safety assessment

-