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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:	Medium for fixing tissue samples.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an *in vitro* 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 INFORMATION

2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to (EC) Regulation 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
2.1.2.	Additional information	
	-	

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*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label 1272/2008 (CLP)	
	Product identification:	BIOFORM S
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	 GHS02  GHS08  GHS06  GHS05
	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.
	Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. 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 COMPOSITION/INFORMATION ON INGREDIENTS

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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	≥ 25%	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	>20%	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.
	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.

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	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.	
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.	

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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 AN 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.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment: Other measures:	Prevent spilling into the sewage system and waterways. -
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.

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	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	2	2.5	-
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:	-	

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	1 mg/m^3 (formaldehyde) 260 mg/m^3 (methanol)	260 mg/m^3 (methanol)	0.5 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

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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	0.47 mg/l (formaldehyde) 154 mg/l (methanol)
Freshwater sediments	2.44 mg/kg (formaldehyde) 570.4 mg/kg (methanol)
Marine water	0.47 mg/l (formaldehyde) 15.4 mg/l (methanol)
Marine sediments	2.44 mg/kg (formaldehyde)
Food chain	No information available
Microorganisms in sewage treatment	0.19 mg/l (formaldehyde) 100 mg/l (methanol)
Soil (agricultural)	0.21 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.

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8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the Directive 89/686/EEC 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 Time until perforation: >240 min
	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.
	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
	Color:	colourless	No information available
	Odor:	sharp	No information available
	Odor threshold:	No information available	No information available
	pH:	7.1 – 7.5	No information available
	Melting point / freezing point;	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	21°C	No information available
	Evaporation rate:	No information available	No information available

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	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapor pressure:	No information available	No information available
	Vapor density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	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).
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:

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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) >2000 mg/kg (methanol)
Dermal:	No information available	rabbit	LD_{50}	No information available	>270 mg/kg (formaldehyde) >12000 mg/kg (methanol)
Inhalation exposure:	No information available	rat	LC_{50}	4 h	0.58 mg/l (formaldehyde) >12000 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
Skin corrosion/irritation	No information available	-	-	-	Causes skin irritation.
Serious irritation to eyes:	No information available	-	-	-	Causes serious eye irritation.

Sensitization

Dermal exposure:	May cause allergic skin reaction.
Inhalation exposure:	Allergic persons may display irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	If swallowed it can cause severe burns to mouth and throat, and danger of esophagus and stomach perforation.
Dermal exposure:	Depending on concentration and exposure time, redness accompanied by sensation of stinging and pain may occur, as well as burns and blistering.

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Inhalation exposure:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and shortness of breath. Inhalation may cause formation of oedema in respiratory tract and may cause damage.
Eye exposure:	Causes serious eye damage. Fumes may cause lacrimal irritation (tearing), blindness hazard.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	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	No information available
Subacute inhalation	No information available	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	No information available
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	No information available
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

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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 *in vitro*:	No information available.
	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.	Practical experiences:	
	Remarks relevant for classification:	No information available
	Other remarks:	No information available
11.3.	General notes:	
	-	

SECTION 12 ECOLOGICAL INFORMATION:

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12.1. Toxicity

Acute (short-term) toxicity	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/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
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	-

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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	-

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	-

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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.	Other adverse effects
	No information available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	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)

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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)	
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:	-

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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:	-
	Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; 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. 2037/200 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	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	
	-	

SECTION 16 Other information			
16.1.	Indication of changes:	-	
16.2.	Abbreviations and acronyms:	PBT	Stable, bioaccumulative and toxic
		vPvB	Strongly stable and strongly bioaccumulative.
		LD50	Lethal dose, 50%
		LC50	Lethal concentration, 50%
		STOT - SE	Specific target organ toxicity - single exposure
		STOT - RE	Specific target organ toxicity - repeated exposure
16.3.	Key literature references and source of data:	-	

Trading name:	**BIOFORM S**				
Product code:	BIOS-OT-X**	Revision date:	24.05.2019.	Version:	3

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
Classification according to CLP		Classification procedure
-		-

16.5.	Relevant H statements (number and full text)		
	H:	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 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

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