


Trading name:	<b>BIOFIX C</b>				
Product code:	BFC-X**	Revision date:	14 November 2022	Version:	4

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>		
1.1.	Product identifier	
	Trading name:	BIOFIX C
	Chemical name:	-
	Catalogue number:	BFC-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Fixative based on ethyl alcohol, chloroform and acetic acid.
	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 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:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

<b>SECTION 2. Hazards identification</b>		
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. 4	H302
	Skin Irrit. 2	H315
	Eye Irrit. 2	H319
	Acute Tox. 3	H331
	Carc. 2	H351
	Repr. 2	H361d
	STOT RE 1	H372
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		

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2.2.	Label elements	
	Product identification:	BIOFIX C
	Identification number:	-
	Authorisation number:	-
	Hazard pictograms:	 <p>GHS02                      GHS06</p> <p>GHS07                      GHS08</p>
	Signal word:	Danger
	Hazard statements:	<p>H225 Highly flammable liquid and vapor.  H302 Harmful if swallowed.  H315 Causes skin irritation.  H319 Causes serious eye irritation.  H331 Toxic if inhaled.  H351 Suspected of causing cancer.  H361d Suspected of damaging the unborn child.  H372 Causes damage to the central nervous system (liver, kidneys) through prolonged or repeated exposure.</p>
	Precautionary statements:	<p>P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke.  P260 Do not breathe dust/fume/gas/mist/vapours/spray.  P280 Wear protective gloves/protective clothing/eye/protection/face protection.  P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.  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.</p>
	Supplemental hazard information (EU):	-
2.3.	Other hazards	

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<b>Endocrine Disrupting Properties:</b>	No known endocrine disrupting properties
<b>Results of PBT and vPvB assessment:</b>	According to the results of its assessment, this substance is not a PBT or a vPvB.

**SECTION 3. Composition/information on ingredients**

CAS/ EC/ Index number	REACH Registration No	Mass %	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- 0147	40 – 60 %	ethanol	Flam. Liq. 2; H225
67-66-3/ 200-663-8/ 602-006-00-4	-	25-30 %	chloroform	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Acute Tox. 3; H331 Carc. 2; H351 Repr. 2; H361d STOT RE 1; H372
64-19-7/ 200-580-7/- 607-002-00-6	-	9 -10 %	acetic acid, 99%	Flam. Liq. 3; H226 Skin Corr. 1B; H314

**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 15 minutes. If the symptoms remain, immediately call in ophthalmologist.	
Following ingestion:	If the afflicted person is vomiting, there may be risk of aspiration. Keep the airways open. Do not induce vomiting. Immediately consult a physician and show the container or label.	

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	Self-protection of the first aider:	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, irritation of the mucous membrane of the nose/throat may occur (burning sensation, urge to sneeze, and runny nose). Very high concentration may cause difficult breathing, shortness of breath, coughing fits, chest tightness, headache, vertigo, and narcosis.
	Following skin contact:	Depending on concentration and exposure time, it may lead to redness, rough and cracked skin.
	Following eye contact:	Depending on concentration and exposure time, mucosa stinging, lacrimation, redness and pain may occur, as well as bleeding, delayed onset of inflammations 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, vertigo, and headache.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

<b>SECTION 5. Firefighting measures</b>		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Water spray, dry powder, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	Water with full jet.
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Formation of toxic gases is possible during heating or in case of fire.
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.	

<b>SECTION 6. Accidental release measures</b>		
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.

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	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 incompatible materials (see Section 10).
6.4.	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal information.	

<b>SECTION 7. Handling and storage</b>		
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:	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.

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	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 9).
<b>7.3.</b>	<b>Specific end use(s)</b>	
	Recommendations:	-
	Industrial sector specific solutions:	-

<b>SECTION 8. Exposure controls/personal protection</b>				
8.1. Control parameters				
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
Chloroform	67-66-3	2/-	10/-	-
Ethanol	64-17-5	1000/-	1900/-	
Acetic acid, glacial	64-19-7	10/20	25/50	
Substance name:	-			
EC No:	-	CAS No:	-	
<b>DNEL</b>				
<b>Industrial</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	1900 mg/m <sup>3</sup> (ethanol)	5 mg/m <sup>3</sup> (chloroform)	2.5 mg/m <sup>3</sup> (chloroform)	380 mg/m <sup>3</sup> (ethanol) 2.5 mg/m <sup>3</sup> (chloroform)
Dermal	-	-	-	343 mg/kg (ethanol) 2.86 mg/kg (chloroform)
Critical physical parameters: solubility, flammability, corrosivity:     -				
<b>Consumer</b>				

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Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	87 mg/kg bw/day (ethanol) 0.33 mg/kg bw/day (chloroform)
Inhalation	950 mg/m <sup>3</sup> (ethanol)	-	-	114 mg/m <sup>3</sup> (ethanol) 0.625 mg/m <sup>3</sup> (chloroform)
Dermal	-	-	-	206 mg/kg (ethanol)

PNEC	
Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol) 0.146 mg/l (chloroform)
Freshwater sediments	3.6 mg/kg (ethanol) 0.45 mg/kg (chloroform)
Marine water	0.79 mg/l (ethanol) 0.015 mg/l (chloroform)
Marine sediments	2.9 mg/kg (ethanol) 0.09 mg/kg (chloroform)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol) 0.048 mg/l (chloroform)
Soil (agricultural)	0.63 mg/kg (ethanol) 0.56 mg/kg (chloroform)
Air	no information available

<b>8.2.</b>	<b>Exposure controls</b>	
<b>8.2.1.</b>	<b>Appropriate engineering controls</b>	
	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.
<b>8.2.2.</b>	<b>Personal protection equipment</b>	

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8.2.2.1.	Eye and face protection:	Safety glasses that stick to face 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 EU 2016/425/EEC and standard EN 374. Full contact: Gloves material: Viton Glove thickness: 0.70 mm Time until perforation: >480 min Splashing: Glove material: butyl rubber Glove thickness: 0.70 mm Time until perforation: > 10 min
	Other skin protection:	Wear full protective suit that protects from chemicals (EN 340) and shoes that cover the entire foot. Choose the protective clothes according to concentration and amount of hazardous substances present at workplace.
8.2.2.3.	Respiratory protection:	Full face mask (EN 136) or half mask (EN 140) equipped with a recommended "AX" filter (EN 371) 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
	Colour:	transparent	No information available
	Odour/odour threshold:	characteristic/no information available	No information available
	Melting point / freezing point:	No information available	No information available



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	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:	22 °C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	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).
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	Heats, sparks, and open flames and other ignition sources.
10.5.	Incompatible materials:	Metals, acetone, oxidants.
10.6.	Hazardous decomposition products:	Hydrogen chloride.

SECTION 11. Toxicological information					
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results

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Oral exposure:	No information available	rat	LD <sub>50</sub>	No information available	7.060 mg/kg (ethanol) 908 mg/kg (chloroform)
Dermal exposure:	No information available	rabbit	LD <sub>50</sub>	No information available	>20.000 mg/kg (ethanol) >75 mg/kg (chloroform)
Inhalation:	No information available	rat	LC <sub>50</sub>	No information available	>8.000 mg/l (ethanol) 3 mg/l (chloroform)

**Specific target organ toxicity – single exposure (STOT SE):**

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

**Aspiration hazard:** No information available

**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	-	-	-	Eye irritation.

**Sensitization**

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

**Symptoms related to the physical, chemical and toxicological characteristics**

Oral exposure:	Depending on concentration and exposure period, it may lead to kidney and liver disorders.
Dermal exposure:	Depending on concentration and exposure time, redness accompanied by sensation of stinging and pain may occur, defatting, skin cracking, rash, swelling, burns, blisters and delayed onset of inflammations.

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Inhalation exposure:	Depending on concentration and exposure period, it may cause vertigo, nausea, disorientation.
Eye exposure:	Depending on concentration and exposure period, it may lead to mucosa stinging, tearing, redness and pain.

Repeated dose toxicity (subacute, subchronic, chronic)						
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	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):						
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	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

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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:	No information available
Mutagenicity <i>in vitro</i> :	No information available
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
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11.2.	Information on other hazards:	
11.2.1.	Endocrine disrupting properties:	
	No known endocrine disrupting properties that affect human health.	No information available
11.2.2.	Other informations:	
	-	

**SECTION 12. Ecological information**

12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	<i>Oryzias latipes</i>	-	1.463 mg/l (chloroform)	-
Crustacea:	EC <sub>50</sub>	48 hours	<i>Daphnia magna</i> (water flea)	-	6.3 mg/l (chloroform)	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	<i>Chlamydomonas reinhardtii</i>	-	3.61 mg/l (chloroform)	-
Other organisms	-	-	-	-	-	-

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Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	-	-	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	-	-	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	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	-

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note

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No information available	No information available	No information available	No information available	-
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Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea ( <i>Daphnia</i> )	EC <sub>50</sub>	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	-
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
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**12.6. Endocrine disrupting properties**

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	Based on available data, does not contain endocrine disruptors.
12.7.	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:
	-

**SECTION 14. Transport information**

	Transporting/shipment by road (ADR)
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, chloroform)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

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Transporting/shipment by rail (RID)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, chloroform)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, chloroform)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, chloroform)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, chloroform)
Transport hazard class(es):	3 (6.1)
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Further information:	-
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<b>SECTION 15. Regulatory information</b>	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations



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	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</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	
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<b>SECTION 16. Other information</b>		
16.1.	Indication of changes:	-

Trading name:	<b>BIOFIX C</b>				
Product code:	BFC-X**	Revision date:	14 November 2022	Version:	4

16.2.	Abbreviations and acronyms:	<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)	
	Classification according to CLP	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H:	<p>225 Highly flammable liquid and vapour.</p> <p>226 Flammable liquid and vapour.</p> <p>302 Harmful if swallowed.</p> <p>314 Causes severe skin burns and eye damage.</p> <p>315 Causes skin irritation.</p> <p>319 Causes serious eye irritation.</p> <p>331 Toxic if inhaled.</p> <p>351 Suspected of causing cancer.</p> <p>361d Suspected of damaging fertility. Suspected of damaging the unborn child.</p> <p>372 Causes damage to organs through prolonged or repeated exposure.</p>
16.6.	Training advice:	-
16.7.	Further information:	<p>"X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>

<b>ANNEX:</b>
<b>EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT</b>
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