

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

SECTION 1. Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trading name:	BIOFIX GL
	Chemical name:	-
	Catalogue number:	BFGL-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in histology.
	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:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+38512348342
	Other information:	-

SECTION 2. Hazards information		
2.1.	Classification of substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Signal word:
	Flam. Liq. 3	H226
	Skin Sens. 1	H317
	Muta. 2	H341
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label contents	
	Product identification:	BIOFIX GL
	Identification number:	-
	Authorisation number:	-

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

Hazard pictograms:		GHS02
		GHS07
		GHS08
Signal word:	Danger	
Hazard statement:	H226 Flammable liquid and vapour. H317 May cause an allergic skin reaction. H341 Suspected of causing genetic defects.	
Precautionary statement:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not smoke. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P308 + P313 IF exposed or concerned: Get medical advice/attention.	
Supplemental hazard information (EU):	-	
2.3.	Other hazards	
	-	

SECTION 3. Composition/information on ingredients

CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610- 43-xxxx	≤ 20%	ethanol	Flam. Liq. 2; H225

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

107-22-2/ 203-474-9/ -	-	< 5%	glyoxal	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1; H317 Acute Tox. 4; H332 Muta. 2; H341
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SECTION 4. First aid measures		
4.1.	Description of first aid measures	
	General notes:	If the symptoms remain, immediately call a physician.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. Provide oxygen if difficult breathing occurs.
	Following skin contact:	Remove the contaminated clothes. Carefully rinse with water for 15 minutes.
	Following eye contact:	Rinse the eyes with a mild stream of water for at least 15 minutes with eyelids wide open.
	Following ingestion:	Thoroughly rinse mouth with water. If the afflicted person is conscious, provide them with copious amounts of water. Seek medical assistance.
	Self-protection of the first aider:	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	May cause eye and upper respiratory system irritation (burning sensation, irritation). May cause bronchoconstriction. Symptoms may include headache, dizziness, drowsiness and loss of consciousness after exposure to high concentration.
	Following skin contact:	Defatting, dry skin.
	Following eye contact:	Splashing may cause sensation of discomfort, burning sensation, conjunctival redness, superficial corneal lesions.
	Following ingestion:	Symptoms may include strong stinging sensation, headache, dizziness, drowsiness and loss of consciousness after exposure to high concentration. In case of denaturants present, dispepsion may occur (such as vomiting).
4.3.	Indication of any immediate medical attention and special treatment needed	
	No information available	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, alcohol-resistant foam, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	Water jet
5.2.	Special hazards arising from the substance or mixture	

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

	Hazardous combustion products:	Incomplete combustion of the product.
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool the closed containers that have been exposed to fire using water spray or steam.	
5.4.	Additional information	
	-	

SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use protective clothes while disposing of smaller amounts. Use self-contained breathing apparatus with compressed air (open circuit) in case of disposing of larger quantities, or a self-contained breathing apparatus with closed circuit.
	Accident prevention methods:	Secure the safe area, remove all ignition sources and in case of emergency contact 112, manufacturer, and distributor. Place warning sign with flame symbols and devices that cause sparking.
	Emergency procedures:	Remove or neutralize all the factors that may worsen the situation, use all the approved means for controlling the situation and use all the recommended personal protection.
6.1.2.	For emergency responders:	
	Use only a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
6.2.	Environmental precautions:	
	Use sand barriers for preventing further spillage of chemicals. Do not dispose of in sewage, drainage system and waterways.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand barriers or barriers made of similar material.
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents.
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and danger of environmental pollution contact 112.
6.4.	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage	
7.1.	Precautions for safe handling
7.1.1.	Protection measures

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use tools that cause sparking.
	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 a well-ventilated place. Keep away from sources of heat and solar radiation.
	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:	-
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	
ethanol	64-17-5	1000/-	1900/-	-
Substance: -				
EC No:	-	CAS No	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	35 mg/kg (ethylene glycol)	950 mg/m ³ (ethanol)

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

Dermal	-	-	-	343 mg/kg (ethanol)
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Critical physical parameters: solubility, flammability, corrosivity:

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)

PNEC

Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	36 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	No information available

8.2. Exposure control

8.2.1. Appropriate engineering controls

Substance/mixture related measures to prevent exposure during identified uses:	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:	See Section 7.2

8.2.2. Personal protective equipment

8.2.2.1.	Eye and face protection:	Protective eyeglasses that stick to face, or a visor in case of lower concentration in air; protective mask that covers the entire face in case of higher concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	In case of thorough contact use butyl rubber gloves (0.4 mm thick). In case of contact with drops use polychlorin gloves (0.1 mm thick). Protective gloves must be according to the EU Directive EU 2016/425/EEC and standard EN 374.

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

	Other skin protection:	During everyday work use cotton clothing and suitable footwear, such as rubber boots or shoes that cover the entire foot. In case of spillage hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	In case of concentration higher than GVI, use full face mask with brown A filter.
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:	light yellow	No information available
	Odor:	sharp	No information available
	Odor threshold:	No information available	No information available
	pH:	3.0 - 5.0	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:	36°C	No information available
	Evaporation rate:	No information available	No information available
	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):	Completely soluble in water	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

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

	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:	The product is stable under normal working and storage conditions.
10.2.	Chemical stability:	The product is stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.
10.4.	Conditions to avoid:	High temperatures, ignition sources, open flame.
10.5.	Incompatible materials:	Oxidants, acids, alkali metals.
10.6.	Hazardous decomposition products:	Nonbiodegradable in case of using in the described way.

SECTION 11. Toxicological information					
11.1.	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	rat	LD ₅₀	-	7,060 mg/kg (ethanol) 7,070 mg/kg (glyoxal)
Dermal exposure:	No information available	rat	LD ₅₀	-	> 2,000 mg/kg (glyoxal)
Inhalation exposure:	No information available	rat	LC ₅₀	4 h (ethanol)	20,000 mg/l (ethanol) 2,410 mg/l (glyoxal)
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral exposure:	No information available		No information available		-
Dermal exposure:	No information available		No information available		-
Inhalation exposure:	No information available		No information available		-

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

	Respiratory irritation:		May cause respiratory system irritation.			
	Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note	
Skin corrosion/irritation:	-	-	-	-	No information available	
Serious eye damage/irritation	-	-	-	-	No information available	
	Sensitization:					
Skin sensitization:		No information available				
Respiratory system sensitization:		No information available				
	Symptoms related to the physical, chemical and toxicological characteristics					
Oral exposure:	Symptoms may include strong stinging sensation, headache, dizziness, drowsiness and loss of consciousness after exposure to high concentration. In case of denaturants present, dispepsion may occur (such as vomiting).					
Dermal exposure:	Defatting, dry skin.					
Inhalation exposure:	May cause eye and upper respiratory system irritation (burning sensation, irritation). May cause bronchoconstriction. Symptoms may include headache, dizziness, drowsiness and loss of consciousness after exposure to high concentration.					
Eye exposure:	Splashing may cause sensation of discomfort, burning sensation, conjunctival redness, superficial corneal lesions.					
	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	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No information available
<i>In vitro</i> mutagenicity:	No information available
Genotoxicity:	No information available
<i>In vivo</i> mutagenicity:	No information available
Germ cell mutagenicity:	suspected of causing genetic defects
Reproductive toxicity:	No information available
Summary of evaluation of the CMR properties:	-

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

11.2.	Practical experiences:	
	Classification observations:	No information available
	Other observations:	No information available
11.3.	General notes:	
	-	

SECTION 12. Ecological information						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	<i>Zebra danio</i>	No information available	760 mg/L	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	-	-
microorganisms	-	-	No information available	No information available	No information available	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
microorganisms	-	-	-	-	-	-
12.2.	Persistence and degradability					
	Abiotic degradation					
	Degradation half-lives	Method			Evaluation	Note
Marine water	No information available	No information available			No information available	-

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

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
-	-	-	-	-

12.3. Bioaccumulative potential						
Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	-	-	-	-	-	-

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
No information available	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 (<i>Daphnia</i>)	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:
	No information available

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

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	No information available	-
Water-air	No information available	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	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:
	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:

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not empty remnants of the product into drains. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmental hazards:	No information available
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmental hazards:	No information available
Special precautions for user:	-
	Transporting/shipment by inland waterways (ADN)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmental hazards:	No information available
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

Environmental hazards:	No information available
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:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmental hazards:	No information available
Special precautions for user:	-
Further information:	
ADR: Special provision 144 - Aqueous solution containing 24% or less alcohol volume, not subjected to classification. IATA: Special provision A58 - Aqueous solution containing 24% or less alcohol volume, not subjected to classification.	

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. 453/2010 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. 2037/2000 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 of 17 November 2008 on waste and repealing certain Directives EC Regulation No. 850/2004 of the European Parliament and Council from 29 June 2004 on 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)

Trading name:	BIOFIX GL				
Product code:	BFGL-X**	Date of compilation:	27.09.2019.	Version:	1

	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	
	no information	

SECTION 16. Other information			
16.1.	Indication of changes:		-
16.2.	Abbreviations and acronyms:	and	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
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:	225 226 315 317 319 332 341	Highly flammable liquid and vapour. Flammable liquid and vapour. Causes skin irritation. May cause allergic skin reaction. Causes serious eye irritation. Harmful if swallowed. Suspected of causing genetic defects.
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
-