


Trading name:	PHLOXINE B, C.I. 45410				
Product code:	PB-P-X**	Revision date:	21 Dec 2022	Version:	4

SECTION 1. Identification of the substance/mixture and of the company/undertaking	
1.1.	Product identifier
	Substance name: PHLOXINE B, C.I. 45410
	EC No: 242-355-6
	Synonyms: Acid Red 92, Eosin 10B, Eosin Blue
	Catalogue number: PB-P-X**
	REACH registration number: -
	CAS No: 18472-87-2
	Index no.: -
1.2.	Relevant identified uses of the substance or mixture and uses advised against
	Uses: For Methylene Blue-Phloxine staining and staining keratin and mucus according to Kreyberg.
	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 information							
2.1.	Classification of the substance or mixture						
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)						
	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">Hazard class and category code:</td> <td style="width: 50%; padding: 5px;">Hazard statements*:</td> </tr> <tr> <td style="padding: 5px;">STOT RE 2</td> <td style="padding: 5px;">H373</td> </tr> <tr> <td style="padding: 5px;">Aquatic Chronic 3</td> <td style="padding: 5px;">H412</td> </tr> </table>	Hazard class and category code:	Hazard statements*:	STOT RE 2	H373	Aquatic Chronic 3	H412
Hazard class and category code:	Hazard statements*:						
STOT RE 2	H373						
Aquatic Chronic 3	H412						
2.1.2.	Additional information						
	-						

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*For full text of Hazard- and EU Hazard-statements: see Section 16	
2.2. Label elements	
Product identification:	Phloxine B, C.I. 45410
Identification number:	-
Authorization no.:	-
Hazard pictograms:	 GHS08
Signal word:	Warning
Hazard statements:	H373 May cause damage to organs through prolonged or repeated exposure. H412 Harmful to aquatic life with long-lasting effects.
Precautionary statements:	P273 Avoid release to the environment. P280 Wear protective gloves/ eye protection/ face protection. P501 Dispose of contents/container in accordance with local regulations.
Supplemental hazard information (EU):	-
2.3. Other hazards	
-	

SECTION 3. Composition/information on ingredients				
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)
18472-87-2	242-355-6	-	3,4,5,6-tetrachloro-2-(1,4,5,8-tetrabromo-6-hydroxy-3-oxoxanthen-9-yl)benzoic acid	90-100%

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:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.
Following skin contact:	Remove contaminated clothing. Immediately wash with copious amounts of water for at least 15 minutes. Seek medical assistance if the symptoms of irritation remain.

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	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.
	Following ingestion:	DO NOT induce vomiting. If the afflicted person is unconscious, do not provide them with anything orally. Seek medical attention in case of irritation or other symptoms.
	Self-protection of the first aider:	-

4.2. Most important symptoms and effects, both acute and delayed

	Following inhalation:	May cause irritation. Prolonged and/or repeated contact may cause irritation.
	Following skin contact:	May cause skin irritation. Prolonged and/or repeated contact may cause irritation and/or dermatitis.
	Following eye contact:	May cause eye irritation. May cause chemical conjunctivitis.
	Following ingestion:	May cause irritation. Prolonged and/or repeated contact may cause irritation.

4.3. Indication of any immediate medical attention and special treatment needed

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SECTION 5. Firefighting measures

5.1. Extinguishing media

	Suitable extinguishing media:	In case of fire use water spray to cool fire expose containers. Use water, dry chemical, chemical foam, or alcohol-resistant foam, or appropriate foam. Use agent most appropriate to extinguish fire.
	Unsuitable extinguishing media:	-

5.2. Special hazards arising from the substance or mixture

	Hazardous combustion products:	-
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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 or vapor.
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5.4. Additional information

	Make sure the water used for extinguishing fire does not contaminate surface water or groundwater.
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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:	Avoid inhaling dust. Avoid contact with the substance. Secure proper ventilation.
	Emergency procedures:	Leave the hazardous area, pay attention to emergency procedures, consult with expert.

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6.1.2.	For emergency responders:	
	-	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system or waterways.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	For creating barriers, covering and sealing:	Cap the drains. Collect, bundle and pump out everything that got spilled. Pay attention to the possible material restrictions (see Sections 7 and 10). Collect in dry form.
6.3.2.	Cleaning up:	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:	-
6.4.	Reference to other sections	
	For indications of waste processing see Section 13.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	-
	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:	Minimize dust formation. Avoid inhaling vapor, dust, mist or gas. Avoid contact with skin, eyes and clothes. Keep in tightly closed container. Avoid swallowing and breathing.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep container tightly closed. Keep in cool, dry and well-ventilated space, away from incompatible substances.
	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

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		proper ventilation.
	Further information on storage conditions:	No information available.
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	
-	-	-	-	-

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	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity:

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available

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Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
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 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:	Use with appropriate ventilation.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection: Safety glasses that stick to face (preventing splashing) or visor.

8.2.2.2. Skin protection

Hand protection: In case of coming into thorough contact, use butyl rubber gloves (0.4 mm thick). In case of contact with drops, use polychlorene gloves (0.1 mm thick).

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 spilling 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: If the concentration level exceeds the GVI values, use full gas mask equipped with brown filter A.

8.2.2.4. Thermal hazards: -

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

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9.1.	Information on basic physical and chemical properties		
	Value	Method	
Physical state:	powder	No information available	
Color:	bright red-brown	No information available	
Odor:	No information available	No information available	
Odour/odour threshold:	No information available	No information available	
Melting point / freezing point:	No information available	No information available	
Boiling point or initial boiling point and boiling range:	No information available	No information available	
Flammability:	No information available	No information available	
Lover and upper explosion limit:	No information available	No information available	
Flash point:	No information available	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: No information available
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: Incompatible material, excess heat, dust generation, high

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		temperatures.
10.5.	Incompatible materials:	Strong oxidizers.
10.6.	Hazardous decomposition products:	Carbon monoxide, carbon dioxide, oxides of nitrogen.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity:

Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀	Exposure time	Results
Oral exposure:	No information available	Rat	LD ₅₀	No information available	275 mg/kg
Dermal exposure:	No information available	No information available	No information available	No information available	-
Inhalation exposure:	No information available	No information available	No information available	No information available	-

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	-

Aspiration hazard: No information available

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	No information available	No information available	-	No information available	No information available
Serious eye damage/irritation	No information available	No information available	-	No information available	No information available

Sensitization

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Dermal exposure:	No information available
Inhalation exposure:	No information available

Symptoms related to the physical, chemical and toxicological characteristics						
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Oral exposure:	Harmful if swallowed.
Dermal exposure:	Harmful by inhalation and in contact with skin.
Inhalation exposure:	Harmful if swallowed.
Eye exposure:	Risk of serious damage to eyes.

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	-
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	-
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	-

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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
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:

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.

11.2.2. Other informations:

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SECTION 12. Ecological information

12.1. Toxicity

Acute (short-term)	Dose	Exposure	Species	Method	Evaluation	Note
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Trading name:	PHLOXINE B, C.I. 45410				
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toxicity		time				
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	-
Other organisms	-	-	-	-	-	-
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	-
Other organisms	-	-	-	-	-	-

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	-

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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	No information available	
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 (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:							
No information available							
Surface tension:							
Value	°C	Concentration	Method	Note			
No information available	No information available	No information available	No information available	-			
Adsorption / desorption							

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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:
	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:
	No information available
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:

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	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. 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:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transport in bulk according to Annex II	-

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of MARPOL 73/78 and the IBC code:	
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
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: -
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:	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, Transport of Hazardous Substances Act

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15.2.	Chemical safety assessment
	None

SECTION 16. Other information		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
16.4.	Relevant H statements (number and full text)	
	H:	373 May cause damage to organs through prolonged or repeated exposure. 412 Harmful to aquatic life with long-lasting effects.
16.5.	Training advice:	-
16.6.	Further information:	** "X" in the product code marks different volumes (different packaging 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
-