

Trading name:	GRAM LUGOL SOLUTION, STABILIZED				
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version:	4

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier	
Trading name:	GRAM LUGOL SOLUTION, STABILIZED
Chemical name:	-
Catalogue number:	GLS-OT-X**
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Uses:	For use in BioGram 4 Gram bacteria staining kit.
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 (REGULATION (EC) No. 1272/2008 (CLP))	
Hazard class and category code:	Hazard statements*:
Not identified as hazardous substance.	-
2.1.2. Additional information	
-	
*For full text of Hazard- and EU Hazard-statements: see Section 16	
2.2. Classification according to EC Directive Nr. 1272/2008 CLP)	
Product identification:	GRAM LUGOL SOLUTION, STABILIZED
Identification number:	-
Authorization no.:	-
Hazard pictograms:	-
Signal word:	-

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Hazard statements:	-
Precautionary statements:	-
Further information:	-
2.3. Other hazards	
-	

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
CAS/EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
25655-41-8/ 607-771-8/ -	-	< 20	Polyvinylpyrrolidone-iodine	Not Classified

SECTION 4 FIRST AID MEASURES	
4.1.	Description of first aid measures
General notes:	-
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 plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.
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. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.
Self-protection of the first aider:	Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed
Following inhalation:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.

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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: Water spray, dry powder, CO ₂ or alcohol-resistant foam
	Unsuitable extinguishing media: No information available
5.2.	Special hazards arising from the substance or mixture
	Hazardous combustion products: No information available
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.
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. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures: Mark the area using proper signs.
6.1.2.	For emergency responders:
	Wear 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.	Bundling, covering of drains; capping procedures: Sand protective barrier or barriers made of similar materials
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.
6.3.3.	Other information: 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.

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6.4.	Reference to other sections
	<p>See Section 7 for information on safe handling.</p> <p>See Section 8 for information on personal protective equipment.</p> <p>See Section 13 for disposal information.</p>

SECTION 7 HANDLING AN STORAGE

7.1.	Precautions for safe handling										
7.1.1.	Protection measures										
	<table border="1"> <tr> <td>Measures to prevent fire:</td> <td>Keep away from sources of heat and ignition. Do not smoke.</td> </tr> <tr> <td>Measures to prevent aerosol and dust generation:</td> <td>Secure proper ventilation.</td> </tr> <tr> <td>Measures to protect the environment:</td> <td>Prevent spilling into the sewage system and waterways.</td> </tr> <tr> <td>Other measures:</td> <td>-</td> </tr> </table>	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.	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:	-		
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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										
	<table border="1"> <tr> <td>Technical measures and storage conditions:</td> <td>Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.</td> </tr> <tr> <td>Packaging materials:</td> <td>Manufacturer's original packaging.</td> </tr> <tr> <td>Requirements for storage rooms and vessels:</td> <td>Keep away from food and drink. Keep the containers tightly closed.</td> </tr> <tr> <td>Advices for storage equipment:</td> <td>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.</td> </tr> <tr> <td>Further information on storage conditions:</td> <td>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).</td> </tr> </table>	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.	Packaging materials:	Manufacturer's original packaging.	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
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7.3.	Specific end use(s)										
	<table border="1"> <tr> <td>Recommendations:</td> <td>-</td> </tr> <tr> <td>Industrial sector specific solutions:</td> <td>-</td> </tr> </table>	Recommendations:	-	Industrial sector specific solutions:	-						
Recommendations:	-										
Industrial sector specific solutions:	-										

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1.	Control parameters								
	<table border="1"> <thead> <tr> <th>Substance</th> <th>CAS No</th> <th>Occupational exposure limit values/short term values</th> <th>Biological limit values</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Substance	CAS No	Occupational exposure limit values/short term values	Biological limit values				
Substance	CAS No	Occupational exposure limit values/short term values	Biological limit values						

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		ppm	mg/m ³	
-	-	-	-	No information available

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
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.	Engineering measures	
	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.

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	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 (preventing splashing) (EN 166) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) 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:	yellow/amber	No information available
	Odor:	neutral	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point:	No information available	No information available

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Initial boiling point and boiling range:	No information available	No information available
Flash point:	No information available	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):	Soluble in water (20 °C)	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.	
10.3. Possibility of hazardous reactions:	No information available.	
10.4. Conditions to avoid:	High temperatures, ignition sources, open flame.	
10.5. Incompatible materials:	Oxidants.	
10.6. Hazardous decomposition products:	No information available.	

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	-	LD ₅₀	-	-

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Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-

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

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Respiratory irritation:	No information available				
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Irritation and corrosion					
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	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	rabbit	-	-	-
Eye irritation:	-	rabbit	-	-	-

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Sensitization					
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Dermal exposure:	No information available				
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Inhalation exposure:	No information available				
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Symptoms related to the physical, chemical and toxicological characteristics					
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Oral exposure:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.				
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Dermal exposure:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.				
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Inhalation exposure:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.				
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Eye exposure:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.				
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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	-

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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	-

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

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

SECTION 12 ECOLOGICAL INFORMATION:

12.1. Toxicity

Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic 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	-	-	-	-	-	-

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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		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		-
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		-

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Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-
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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

Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-water	No information available	information available	No information available	No information available	No information available	-
Water-air	No information available	information available	No information available	No information available	No information available	-
Soil-air	No information available	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. Other adverse effects

No information available						
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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.						
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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:
	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:	-
Environmentally hazardous:	-
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:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-

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Environmentally hazardous:	-
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:	-
Environmentally hazardous:	-
Special precautions for user:	-
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:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information: The product is not subject 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:	<p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</p>

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	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
	None

SECTION 16 Other information											
16.1.	Indication of changes: -										
16.2.	Abbreviations and acronyms: <table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD₅₀</td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC₅₀</td> <td>Lethal concentration, 50%</td> </tr> <tr> <td>STOT-SE</td> <td>Specific target organ toxicity - single exposure</td> </tr> </table>	PBT	Stable, bioaccumulative and toxic	vPvB	Strongly stable and strongly bioaccumulative.	LD ₅₀	Lethal dose, 50%	LC ₅₀	Lethal concentration, 50%	STOT-SE	Specific target organ toxicity - single exposure
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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)										
	<table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Classification</td> <td>Classification procedure</td> </tr> <tr> <td>-</td> <td>-</td> </tr> </table>	Classification	Classification procedure	-	-						
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-	-										
16.5.	Relevant H statements (number and full text)										
	H: -										
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>										

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT
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