

Trading name:	SACCOMANNO FIXATIVE				
Product code:	SF-OT-X**	Revision date:	27.05.2019.	Version:	2

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1.	Product identifier	
	Trading name:	SACCOMANNO FIXATIVE
	Chemical name:	-
	Catalogue number:	SF-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Solution for fixation and transport of cytology samples.
	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 (EC) Regulation No. 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Flam. Liq. 2	H225
	Acute Tox. 4	H302
	Acute Tox. 4	H312
	Acute Tox. 4	H332
	STOT SE 3	H336
	STOT SE 2	H371
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label 1272/2008 (CLP)	
	Product identification:	SACCOMANNO FIXATIVE

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Identification number:	-
Authorization no.:	-
Hazard pictograms:	 GHS02  GHS07  GHS08
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor H302 Harmful if swallowed. H312 Harmful in contact with skin. H332 Harmful if inhaled. H336 May cause drowsiness or dizziness. H371 May cause damage to organs.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P308+P311 IF exposed or concerned: Call a POISON CENTER/doctor.
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)

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64-17-5/ 200-578-6/ 603-002-00-5	-	≥ 40	ethanol	Flam. Liq. 2; H225
67-56-1/ 200-659-6/ 603-001-00-X	-	< 2.5	methanol	Flam. Liq. 2; H225 Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 STOT SE 1; H370
67-63-0/ 200-661-7/ 603-117-00-0	-	< 2	propan-2-ol	Flam. Liq. 2; H225 Eye Dam. 1; H318 STOT SE 3; H336

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. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Thoroughly wash with water for 15 minutes.
	Following eye contact:	Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open. If the afflicted person wears contact lenses that are easy to remove, remove the lenses and continue rinsing.
	Following ingestion:	Rinse the mouth thoroughly with water. If the afflicted person is conscious, provide them with 1-2 glasses of water. DO NOT induce vomiting. Consult a physician.
	Self-protection of the first aider:	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	May cause eye irritation and upper respiratory system (stinging sensation, irritation). Bronchoconstriction is possible. Possible symptoms include CNS symptoms such as headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration.
	Following skin contact:	Defatting, dry skin.
	Following eye contact:	Splatter may cause discomfort, stinging sensation, conjunctival redness, and corneal surface lesions.
	Following ingestion:	It may lead to occurrence of strong sensation of stinging, headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration. If denaturants are present, dyspepsia may occur (such as vomiting).
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:	Small fire - water spray, dry powder, alcohol-resistant foam, CO ₂ Large fire - water spray or alcohol-resistant foam.
	Unsuitable extinguishing media:	-
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	-
5.3.	Advice for firefighters	
	Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing).	
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:	When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus.
	Accident prevention methods:	Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks.
	Emergency procedures:	Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection.
6.1.2.	For emergency responders:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents

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6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112).
6.4.	Reference to other sections	
	-	

SECTION 7 HANDLING AN STORAGE		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use tools that cause sparks.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation. Do not inhale vapors or mist.
	Environmental precautions:	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 heat and direct 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/-	No information available

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Methanol	67-56-1	200/-	260/-	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*), end-of-shift urinary excretion
2-propanol	67-63-0	400/500	999/1250	No information available

* For all results pertaining creatinine levels, creatinine concentration < 0.5 g/l and > 3.0 g/l may not be taken into consideration

Substance name:	-			
EC No:	-	CAS No:	-	

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
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. Appropriate engineering controls

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	Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment.
	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 protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses (gas proof) that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
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) (EN 374).
	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 – EN 465) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values (in the case of inadequate ventilation), use full gas mask (EN 136) equipped with brown and green filter AK.
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			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available

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	Color:	colourless	No information available
	Odor:	ethanolic	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
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	26°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):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2.	Other information		
	-		

SECTION 10 STABILITY AND REACTIVITY		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	May cause hazardous reactions in contact with strong bases.
10.4.	Conditions to avoid:	High temperatures, ignition sources, open flame, closed, unventilated rooms.
10.5.	Incompatible materials:	Oxidants, acids, bases, alkali metals.
10.6.	Hazardous decomposition products:	Carbon oxides.

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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	No information available	8,000 mg/kg (ethanol) 1,187 - 2,769 mg/kg (methanol) >2,000 mg/kg (2-propanol)
Dermal exposure:	No information available	rabbit	LD ₅₀	24 h	2,000 mg/kg (ethanol) 17,000 mg/kg (methanol) >2,000 mg/kg (2-propanol)
Inhalation exposure:	No information available	rat	LC ₅₀	4h	6,200 mg/kg (ethanol) 20 mg/l (2-propanol)
	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:		May cause respiratory irritation.		
	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				
Dermal exposure:	No information available				
Inhalation exposure:	No information available				

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Symptoms related to the physical, chemical and toxicological characteristics						
Oral exposure:	It may lead to occurrence of strong sensation of stinging, headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration. If denaturants are present, dyspepsia may occur (such as vomiting).					
Dermal exposure:	Defatting, dry skin.					
Inhalation exposure:	May cause eye irritation and upper respiratory system (stinging sensation, irritation). Bronchoconstriction is possible. Possible symptoms include CNS symptoms such as headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration.					
Eye exposure:	Splatter may cause discomfort, stinging sensation, conjunctival redness, corneal surface 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	-
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	
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 (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-

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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
91	1	OECD (anaerobic conditions)	-	ethanol

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	pH	°C	Method	Evaluation	Note
- 0.31	-	-	25	-	-	ethanol

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0.05	-	-	25	-	-	2-propanol
-0.74	-	-	25	-	-	methanol

Bioconcentration factor (BCF)						
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Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

Chronic ecotoxicity						
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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
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	-

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Soil-air	No information available	No information available	No information available	No information available	-
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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:

	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances
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13.1.3. Waste treatment – relevant information:

	No information available
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13.1.4. Sewage disposal – relevant information:

	Waste must not be disposed of into the sewage system.
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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.
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13.1.6. Relevant Community provisions:

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SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
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UN number:	1170
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UN proper shipping name:	Ethanol solution
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Transport hazard class(es):	3
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Packing group:	III
Environmentally hazardous:	-
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
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
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
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:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	
-	

SECTION 15 REGULATORY INFORMATION

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15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 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 from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment	
	None	

SECTION 16 Other information		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative. LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT-SE Specific target organ toxicity - single exposure
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		Classification procedure

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16.5.	Relevant H statements (number and full text)		
	H:	225 301+311+331 302+312+332 318 336 370 371	Highly flammable liquid and vapor. Toxic if swallowed, in contact with skin or if inhaled. Harmful if swallowed, in contact with skin or if inhaled . Causes serious eye damage. May cause drowsiness or dizziness. Causes damage to organs. May cause damage to organs.
16.6.	Training advice:		-
16.7.	Further information:		** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT
-