

Trade name:	BIOCLEAR NEW				
Product code:	BCN-X**	Date of compilation:	15 Feb 2019	Version:	5


SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier	
Trade name:	BioClear New
Chemical name:	-
Catalogue number:	BCN-X**
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Uses:	Xylene substitute for tissue processing, deparaffinization and clearing.
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
Telefax:	+385 1 2404039
e-mail of competent person:	msds@biognost.hr
National contact:	-
1.4. Emergency telephone numbers	
National Protection and Rescue Directorate:	112
Medical information:	+385 1 2348 342
Other information:	-

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture	
2.1.1. Classification according to Regulation (EC) No 1272/2008 (CLP)	
Hazard class and category code:	Warning statements*:
Aspir. Tox. 1	H304
2.1.2. Additional information	
EUH066	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16	
2.2. Label elements	
Product identification:	BioClear New
Identification number:	-
Authorisation number:	-

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Hazard pictograms:	
	GHS08
Signal word:	Danger
Hazard statement:	H304 May be fatal if swallowed and enters airways. EUH066 Repeated exposure may cause skin dryness or cracking.
Precautionary statements:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P331 Do NOT induce vomiting. P370+P378 In case of fire: Use water fog, foam, dry chemical or carbon dioxide (CO ₂) for extinction. P403+P235 Store in a well-ventilated place. Keep cool.
Supplemental hazard information (EU):	-
2.3. Other hazards	
	-

SECTION 3. Composition/information on ingredients				
CAS/EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
-/ 920-901-0/ -	01-2119456810-40	100%	Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	Aspir. tox. 1; H304 EUH066

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. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation.

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Following skin contact:	Remove contaminated clothing. Thoroughly wash with water and soap 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. Contact a physician if irritation occurs.
Following ingestion:	DO NOT induce vomiting. Seek immediate medical attention.
Self-protection of the first aider	-

4.2.	Most important symptoms and effects, both acute and delayed	
Following inhalation:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.	
Following skin contact:	Prolonged and/or repeated exposure to low viscosity content may cause skin dryness or cracking. May be irritating to the eyes, nose, throat and lungs.	
Following eye contact:	Eye irritation may occur during exposure to vapor concentrations above recommended level.	
Following ingestion:	If swallowing occurs, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.	
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Water spray, foam, dry powder, CO ₂
	Unsuitable extinguishing media:	Straight streams of water
5.2.	Special hazards arising from the substance or mixture	
	Hazardous by products of fire:	Smoke, fume, incomplete combustion products, carbon oxydes.
5.3.	Advice for firefighters	
	Evacuate the area. 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). Use water spray to cool fire exposed surfaces and to protect personnel.	
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	

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	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 materials 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
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	
		See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.

SECTION 7. Handling and 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.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	

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Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating. Avoid skin contact.	
7.2. Conditions for safe storage, including any incompatibilities	
Technical measures and storage conditions:	Keep in a cool and well-ventilated place. Keep away from heat and direct solar radiation.
Packaging materials:	Teflon, polypropylene, stainless steel, carbon steel.
Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed. Store in a cool, well-ventilated area.
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:	Suitable materials and coating are teflon, polypropylene, polyethylene, stainless steel, carbon steel. Unsuitable materials and coatings include ethylene propylene diene monomer (EPDM), natural rubber, polystyrene, butyl rubber.
7.3. Specific end use(s)	
Recommendations:	This product attracts static electricity that may cause electrical sparking (ignition source) that may ignite flammable vapors of the liquid. The liquid is usually an isolator if its conductivity level is under 100 pS/m. It is considered a semiconductor that attracts static electricity if its conductivity level is less than 10,000 pS/m. Regardless of the type of the liquid (isolator or semiconductor), precautions are the same. Numerous factors, such as the liquid temperature, contaminants, antistatic additives and filtration may severely influence the liquid conductivity.
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	
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	-	171*	1200*	No information available
* Source - material safety data sheet provided by the raw materials supplier				
Substance:	-			
EC No:	-	CAS No:	-	
DNEL				

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Industrial				
Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer				
Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
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	
	Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment. Wash hands after handling the product and before eating and/or drinking.
	Structural measures to prevent exposure:	Adequate ventilation should be provided so that exposure limits are not exceeded. Use explosion-proof ventilation equipment.
	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:	

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8.2.2.1.	Eye and face protection:	Safety glasses 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 prolonged or repeated contact with the product, use nitril rubber protective gloves (EN 374).
	Other skin protection:	Wear full protective suit that protects from chemicals (EN 340) and 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 (or because of inadequate ventilation), use full gas mask (EN 136) equipped with a recommended filter type A.
8.2.2.4.	Thermal hazards:	No information available.
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties

9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour:	faint	No information available
	Odour 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:	170 - 250 °C	No information available
	Flash point:	62 °C	No information available
	Evaporation rate:	0,05 (n-Butyl acetate = 1)	No information available
	Flammability (solid, gas):	No information available	No information available

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Upper/lower flammability or explosive limits:	lower: 0.6 upper: 7.0	No information available
Vapour pressure:	0.04 kPa (0.3 mm Hg) at 20 °C	No information available
Vapour density:	> 1 at 101 kPa (Air = 1)	No information available
Relative density	0.731 – 0.851 (15 °C)	No information available
Bulk density:	No information available	No information available
Solubility(ies):	Negligible	No information available
Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
Auto-ignition temperature:	> 200 °C	No information available
Decomposition temperature:	No information available	No information available
Viscosity:	1.3 cSt (1.3 mm ² /sec) at 20 °C 2.5 cSt (2.5 mm ² /sec) at 20 °C	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:	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:	Hazardous polymerization will not occur.
10.4.	Conditions to avoid:	Open flames and high energy ignition sources.
10.5.	Incompatible materials:	Strong oxidants.
10.6.	Hazardous decomposition products:	Product decomposition will not occur at ambient temperature.

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:	No information available	rat	LD ₅₀ > 5000 mg/kg	-	Minimal toxicity.
Dermal:	No information available	rabbit	LD ₅₀ > 5000 mg/kg	-	Minimal toxicity.

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Inhalation:	No information available	rat	LC ₅₀ > 5000 mg/kg	4 h	Minimal toxicity.
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Specific target organ toxicity - single exposure (STOT-SE):

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

Aspiration hazard: Insignificant danger at normal handling temperature.

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	No information available	rabbit	Not irritating.	OECD	-
Serious eye damage/irritation	No information available	rabbit	Not irritating.	not specified	-

Sensitization

Skin sensitization:	Not expected to be a skin sensitizer.
Respiratory sensitization:	Not expected to be a respiratory sensitizer.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	If swallowing occurs, aspiration of the vomit may also occur and cause chemical pneumonitis or pulmonary oedema.
Dermal exposure:	Prolonged and/or repeated exposure to low viscosity content may cause irritation and dermatitis, skin drying or cracking.
Inhalation exposure:	Respiratory system irritation, headache, vertigo, nausea and faint may occur during exposure to vapor concentrations above recommended level. It may also act as an anesthetic and affect central nervous system.
Eye exposure:	Eye irritation may occur during exposure to vapor concentrations above recommended level.

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	-

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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 carcinogenicity studies were made, but since the product is not mutagenic and causes a minimal level of toxicity, it can be assumed that chronic exposure will not cause tumors.
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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:	
Classification observations:	No information available
Other observations:	No information available
11.3. General notes:	
Vapour concentration above recommended exposure levels are irritating to the eyes and the respiratory tract, may cause headaches and dizziness, are anesthetic may have other central nervous system effects. Prolonged and/or repeated skin contact with low viscosity materials may defat skin resulting in possible irritation and dermatitis. Small amounts of liquid aspirated into the lungs during ingestion or from vomiting may cause chemical pneumonitis or pulmonary edema.	

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	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	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	No information available

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Crustacea:	EC ₅₀	48 hours	No information available	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	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	No information available

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log K_{ow})

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
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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	Not expected.
Chronic toxicity on crustacea (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	Not expected.

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:					
Surface tension:					
Value	°C	Concentration	Method	Note	
No information available	No information available	No information available	No information available	-	

Adsorption / desorption

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-Water	No information available	No information available	No information available	No information available	-
Water-Air	No information available	No information available	No information available	No information available	-
Soil-Air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

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No information available

12.6.	Other adverse effects
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No information available

SECTION 13. Disposal considerations

13.1.	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
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Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection. 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.

13.1.2.	Waste codes/waste designations according to Law:
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European Waste Code: 08 XX XX These codes are assigned based upon the most common uses for this material and may not reflect contaminants resulting from actual use. Waste producers need to assess the actual process used when generating the waste and its contaminants in order to assign the proper waste disposal code(s).

13.1.3.	Waste codes/waste designations according to Law:
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Incinerating the product at high temperatures is recommended in order to avoid incomplete combustion products.
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13.1.4.	Sewage disposal – relevant information:
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Waste must not be disposed of into the sewage system.

13.1.5.	Other disposal recommendations:
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Empty Container Warning: Empty containers may contain residue and can be dangerous. Do not attempt to refill or clean containers without proper instructions. Empty drums should be completely drained and safely stored until appropriately reconditioned or disposed. Empty containers should be taken for recycling, recovery or disposal through suitably qualified or licensed contractor and in accordance with governmental regulations. Do not pressurise, cut, weld, braze, solder, drill, grind or expose such containers to heat, flame, sparks, static electricity or other sources of ignition. They may explode and cause injury or death.
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13.1.6.	Relevant Community provisions:
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SECTION 14. Transport information

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Transporting/shipment by road (ADR)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
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 hazards:	-
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 hazards:	-
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 hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 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 hazards:	-

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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
	Authorisations and/or restrictions on use
	Authorisations: -
	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 of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 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)
	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: -

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16.2.	Abbreviations and acronyms:	and	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
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	
	-		-	
16.5.	Relevant H statements (number and full text)			
	H:	304 (EUH066)	May be fatal if swallowed and enters airways. Repeated exposure may cause skin dryness or cracking.	
16.6.	Training advice:		-	
16.7.	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	
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