

Trading name:	TB CARBOL FUCHSIN REAGENT			
Product code:	TBC-OT-X**	Date of compilation:	13 June 2019	Version: 4

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	TB CARBOL FUCHSIN REAGENT
	Chemical name:	-
	Catalogue number:	TBC-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in TB-Stain Cold and TB-Stain Hot 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
	Telefax.:	+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 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:	Hazard statements*:
	Flam. Liq. 3	H226
	Muta. 2	H341
	Acute Tox. 3	H331
	Acute Tox. 3	H311
	Acute Tox. 3	H301
	Skin. Corr. 1B	H314
	STOT RE 2	H373
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		

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2.2	Label elements	
	Product identification:	TB CARBOL FUCHSIN REAGENT
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	 GHS02  GHS05  GHS06  GHS08
	Signal word:	Danger
	Hazard statements:	H226 Flammable liquid and vapor. H314 Causes severe skin burns and eye damage. H301 Toxic if swallowed. H311 Toxic in contact with skin. H331 Toxic if inhaled. H341 Suspected of causing genetic defects. H373 May cause damage to organs through prolonged or repeated exposure.
	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. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.
	Supplemental hazard information (EU):	-
2.3	Other hazards	
	-	

SECTION 3. Composition/information on ingredients

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CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610- 43-xxxx	< 20 %	ethanol	Flam. Liq. 2; H225
107-21-1/ 203-473-3/ 603-027-00-1	-	< 20 %	ethylene glycol	Acute Tox. 4; H302
108-95-2/ 203-632-7/ 604-001-00-2	01-2119471329- 32-xxxx	< 10 %	phenol	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Skin Corr. 1B ; H314 Muta. 2; H341 STOT SE 2; H373

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. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.

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	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Water, foam, dry powder, CO ₂
	Unsuitable extinguishing media:	No information available
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Mixture with combustible ingredients. Forms explosive mixtures with air at elevated temperatures. Development of hazardous combustion gases or vapours possible in the event of fire. Vapours are heavier than air and may spread along floors.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. 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. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not let product enter drains. Risk of explosion.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Cover drains. Collect, bind, and pump off spills.

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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. 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:	Secure proper ventilation. Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge. 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:	Protect against electrostatic charges.
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 tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.
	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.

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	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 10).
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/-	-
Ethylene glycol	107-21-1	20/40	52/104	
Phenol	108-95-2	2/4	8/16	120 mg/g of creatinine (0.14 mol/mol of creatinine), end of shift, urinary excretion
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	1900 mg/ m ³ (ethanol)	-	35 mg/kg (ethylene glycol)	950 mg/m ³ (ethanol) 8 mg/ m ³ (phenol)
Dermal	-	-	-	343 mg/kg (ethanol) 106 mg/kg (ethylene glycol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	87 mg/kg (ethanol)
Inhalation	950 mg/ m ³ (ethanol)	-	7 mg/kg (ethylene glycol)	114 mg/m ³ (ethanol)

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Dermal	-	-	-	206 mg/kg (ethanol) 1.23 mg/kg (phenol) 53 mg/kg (ethylene glycol)
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PNEC	
Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol) 10 mg/l (ethylene glycol) 0.0077 mg/l (phenol)
Freshwater sediments	3.6 mg/kg (ethanol) 37 mg/kg (ethylene glycol) 0.09125 mg/kg (phenol)
Marine water	0.79 mg/l (ethanol) 1 mg/l (ethylene glycol) 0.00077 mg/l (phenol)
Marine sediments	3.7 mg/kg (ethylene glycol) 0.00915 mg/kg (phenol)
Food chain	no information available
Microorganisms in sewage treatment	199.5 mg/l (ethylene glycol) 2.1 mg/l (phenol)
Soil (agricultural)	0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene glycol) 0.136 mg/kg (phenol)
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 the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	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. Secure stations for rinsing eyes and showering.
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:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Full contact: Glove material: butyl rubber Glove thickness: 0.70 mm Break through time: > 480 min Splash contact: Gloves material: nitrile rubber Glove thickness: 0.40 mm Break through time: >120 min
	Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) 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:	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
	Colour:	dark pink	No information available
	Odour:	phenol like	No information available
	Odor threshold:	No information available	No information available

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	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:	48°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
	Vapour pressure:	No information available	No information available
	Vapour 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 (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		
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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:	No information available
10.4	Conditions to avoid:	Heating.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

SECTION 11. Toxicological information	
11.1	Information on toxicological effects
	Acute toxicity:

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Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat	LD ₅₀	-	10.470 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol)
Dermal:	-	rat	LD ₅₀	-	>3.500 mg/kg (ethylene glycol) 660 mg/kg (phenol)
Inhalation:	-	rat	LC ₅₀	4 h	124.7 mg/l (ethanol)

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: No information available.

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	in vitro study	-	OECD 431	causes burns (phenol)
Serious eye damage/irritation	-	rabbit	-	OECD 405	corrosive (phenol)

Sensitization

Skin sensitization:	No information available.
Respiratory sensitization:	No information available.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	No information available.
Dermal exposure:	No information available.
Inhalation exposure:	No information available.
Eye exposure:	No information available.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
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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	-

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)

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	Carcinogenicity:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
	Genotoxicity:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
	Reproductive toxicity:	Based on available data, the classification criteria are not met.
	Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
11.2	Practical experiences:	
	Classification observations:	No information available
	Other observations:	No information available
11.3	General notes:	
	-	

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Leuciscus idus (Golden orfe; ethanol) Oncorhynchus mykiss (rainbow trout; phenol)	-	-	8.140 mg/l (ethanol) 5.0 mg/l (phenol)
Crustacea:	EC ₅₀	48 hours	Daphnia magna (Water flea)	-	-	9.268-14.221 mg/l (ethanol) >100 mg/l (ethylene glycol) 3.1 mg/l (phenol)
Algae/aquatic plants	IC ₅₀	7 days	green algae	-	-	5.000 mg/l (ethanol) 6.500-13.000 mg/l (ethylene glycol) 61.1 mg/l (phenol)
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

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Fish	LC ₅₀	96 hours	No information available	-	-	-
Crustacea:	EC ₅₀	48 hours	No information available	-	-	-
Algae/aquatic plants	IC ₅₀	72 hours	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
94% (ethanol)	No information available	OECD 301E	No information available	readily biodegradable
85% (phenol)	14 days	OECD 301C	No information available	readily biodegradable

12.3 Bioaccumulative potential

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

Value	Concentration	pH	°C	Method	Evaluation	Note
-0,31 (ethanol)	-	-	-	experimental	-	bioaccumulation is not expected
1.47 (phenol)	-	-	30 °C	ECHA	-	bioaccumulation is not expected

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
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No information available	No information available	No information available	No information available	-

Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4	Mobility in soil				
	Known or predicted distribution in environmental compartments:				
	No information available				
	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				
	Not applicable.				

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12.6	Other adverse effects
	No further relevant 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:
	15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	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.
13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.
SECTION 14 TRANSPORT INFORMATION	
	Transporting/shipment by road (ADR)
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	1992

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UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
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:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Further information:	-
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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:	-

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	Restrictions:	-
	Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; 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.
		LD ₅₀	Lethal dose, 50%
		LC ₅₀	Lethal concentration, 50%
		TCOJ	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)		

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	13 June 2019	Version:	4

	H225	Highly flammable liquid and vapor.
	H226	Flammable liquid and vapor.
	H301	Toxic if swallowed.
H:	H302	Harmful if swallowed.
	H311	Toxic in contact with skin.
	H314	Causes severe skin burns and eye damage.
	H331	Toxic if inhaled.
	H341	Suspected of causing genetic defects.
	H373	May cause damage to organs through prolonged or repeated exposure.
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	
-	

Trading name:	TB DECOLORIZER			
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version: 4

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	TB DECOLORIZER
	Chemical name:	-
	Catalogue number:	TBD-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in TB-Stain Cold and TB-Stain Hot 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
	Telefax.:	+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 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:	Hazard statements*:
	Flam. Liq. 2	H225
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	TB DECOLORIZER
	Identification number:	-
	Authorization number:	-

Trading name:	TB DECOLORIZER			
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Hazard pictograms:	
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
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.
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)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- xxxx	≥ 60%	ethanol	Flam. Liq. 2; H225
7647-01-0/ 231-595-7/ 017-002-00-2	01-2119484862-27- xxxx	<3 %	hydrochloric acid, 37%	Skin Corr. 1A; H314 Acute Tox. 3; H331

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. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.

Trading name:	TB DECOLORIZER				
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	Following ingestion:	Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Formation of toxic gases is possible during heating or in case of fire.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. 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. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version:	4

	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways 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 absorbing material. 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:	Secure proper ventilation. Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. 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:	Protect against electrostatic charges.
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 tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.

Trading name:	TB DECOLORIZER			
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version: 4

	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 10).
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/-	-
Hydrogen chloride	7647-01-0	5/10	8/15	-
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	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version:	4

PNEC	
Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	no information available

8.2 Exposure controls

8.2.1. Appropriate engineering controls

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.
Structural measures to prevent exposure:	In accordance with Section 7.
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. Secure stations for rinsing eyes and showering.

8.2.2. Personal protection equipment

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:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) 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.

Trading name:	TB DECOLORIZER			
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version: 4

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
	Colour:	colourless	No information available
	Odour:	ethanol like	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:	17 °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
	Vapour pressure:	No information available	No information available
	Vapour 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):	1 g/l (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

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	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:	No dangerous reactions known.
10.4	Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

SECTION 11. Toxicological information					
11.1	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat	LD ₅₀	-	7.060 mg/kg (ethanol)
Dermal:	-	-	-	-	-
Inhalation:	-	rat	LC ₅₀	4 h	20.000 mg/l (ethanol) 4.74 mg/l (hydrochloric acid)
	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:		No information available.		
	Irritation and corrosion				

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version:	4

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-

Sensitization

Skin sensitization:	No information available.
Respiratory sensitization:	No information available.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	No information available.
Dermal exposure:	No information available.
Inhalation exposure:	No information available.
Eye exposure:	No information available.

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	-

Trading name:	TB DECOLORIZER				
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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):
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	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	-

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	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)
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	Carcinogenicity:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
	Genotoxicity:	Based on available data, the classification criteria are not met.
	Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
	Reproductive toxicity:	Based on available data, the classification criteria are not met.

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	Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
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11.2	Practical experiences:
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	Classification observations:	No information available
	Other observations:	No information available

11.3	General notes:
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Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version:	4

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	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	4 days	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

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version:	4

No information available	No information available	No information available	No information available	No information available

12.3 Bioaccumulative potential

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

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

Chronic ecotoxicity

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4 Mobility in soil

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

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version:	4

	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
	Not applicable.

12.6	Other adverse effects
	No further relevant information available.

SECTION 13. Disposal considerations

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

13.1.2.	Waste codes/waste designations according to Law:
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3.	Waste treatment – relevant information:
	No information available

13.1.4.	Sewage disposal – relevant information:
	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.

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version:	4

13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
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:	II
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:	II
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:	II
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

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	13 June 2019	Version:	4

UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
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:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; 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:	-

Trading name:	TB DECOLORIZER				
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16.2	Abbreviations and acronyms:	PBT	Stable, bioaccumulative and toxic
		vPvB	Strongly stable and strongly bioaccumulative.
		LD ₅₀	Lethal dose, 50%
		LC ₅₀	Lethal concentration, 50%
		TCOJ	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:	H225	Highly flammable liquid and vapor.
		H314	Causes severe skin burns and eye damage.
		H331	Toxic if inhaled.
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
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Trading name:	TB MALACHITE GREEN REAGENT			
Product code:	TBM-OT-X**	Date of compilation:	11 June 2019.	Version: 3

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1.	Product identifier	
	Trading name:	TB MALACHITE GREEN REAGENT
	Chemical name:	-
	Catalogue number:	TBM-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in TB-Stain Cold 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:	TB MALACHITE GREEN REAGENT
	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)
2437-29-8/ 219-441-7/ 602-096-00-5	-	< 0.25%	bis[[4-[4-(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium]oxalate, dioxalate	Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410

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:	Allergic persons may display irritation after prolonged or repeated exposure.
	Following skin contact:	Allergic persons may display irritation.
	Following eye contact:	May cause irritation.
	Following ingestion:	Swallowing may cause discomfort in abdomen and abdominal pains.

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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, 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.	Bunding, 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
	See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal information.

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 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:	-
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 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).
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

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

Substance name:	-
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EC No:	-	CAS No:	-
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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:	blue-green	No information available
	Odor:	no odor	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:	No information available.
10.5.	Incompatible materials:	No information available.
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	-	-

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	-

Respiratory irritation:	No information available
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Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	rabbit	-	-	-
Eye irritation:	-	rabbit	-	-	-

Sensitization

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

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Swallowing may cause discomfort in abdomen and abdominal pains.
Dermal exposure:	Allergic persons may display irritation.
Inhalation exposure:	Allergic persons may display irritation after prolonged or repeated exposure.
Eye exposure:	May cause irritation.

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	-

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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):					
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	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	-

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	CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)					
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	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

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	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 (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	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
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					

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	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	-
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	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. 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					

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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:	-
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)

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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: 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)

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	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. 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:	H302 H318 H361 H400 H410	Harmful if swallowed. Causes serious eye damage. Suspected of damaging fertility. Suspected of damaging the unborn child. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
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	
-	