

TB-STAIN ECO KIT

The kit contains:

TB Fuchsin reagent

TB Decolorizer


Methylene Blue Loeffler reagent

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

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)				
	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">Hazard class and category code:</td> <td style="padding: 5px;">Hazard statements*:</td> </tr> <tr> <td style="padding: 5px;">Flam. Liq. 2</td> <td style="padding: 5px;">H225</td> </tr> </table>	Hazard class and category code:	Hazard statements*:	Flam. Liq. 2	H225
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: -				

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Hazard pictograms:	
	GHS02
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statements:	P210 Keep away from heat, hot sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
Supplemental hazard information (EU):	-
2.3 Other hazards	
<p>The product has no other known specific hazards for human or environment.</p> <p>Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.</p> <p>Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.</p>	

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- 0147	70 - 90 %	ethanol	Flam. Liq. 2; H225
7647-01-0/ 231-595-7/ 017-002-00-2	-	2 -3 %	hydrochloric acid, 37%	Skin Corr. 1B; H314 STOT SE 3; H335

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:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.

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	Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 10 minutes). If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Place the victim in a comfortable position. Rinse the mouth with clean water. If the victim is conscious induce vomiting. Do not give the victim anything orally, and do not induce vomiting if the victim is unconscious or suffers from convulsions.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.
	Following eye contact:	May irritate the eyes.
	Following ingestion:	Ingestion of larger quantities may affect the central nervous system.
4.3	Indication of any immediate medical attention and special treatment needed	
	If larger quantities have entered the body, obtain medical treatment (gastric lavage, activated carbon).	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Extinguishing powder, alcohol-resistant foam, water, carbon-dioxide.
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Highly flammable liquid and vapour. In case of fire, smoke, and other combustion products (carbon monoxide, carbon dioxide) may be formed, the inhalation of such combustion products can have serious adverse effects on health. Vapours may form an explosive mix with air. Vapours may be ignited by open flames, sparks, electrical equipment, or static charge. Vapours may travel to great distances, ignite in contact with ignition sources and flash back to the primer source (container). Vapours of ethyl alcohol mix greatly with air and may form an explosive mixture. Air containing 3.3 – 19 % ethyl alcohol vapours may explode in contact with ignition sources. Diluting the mixture with large amounts of water results in the loss of its flammability (around 10 % concentration of ethyl alcohol).
5.3	Advice for firefighters	
	Wear full protective clothing and self-contained breathing apparatus. Cool the fire affected containers with water spray. Use water spray to dissipate alcohol vapours.	

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5.4	Additional information
	-

SECTION 6. Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures
6.1.1.	For non-emergency personnel
	Protective equipment: Use personal protective equipment (see Section 8).
	Accident prevention methods: Evacuate members of all non-essential personnel and those members without protective equipment.
	Emergency procedures: Mark the area using proper signs.
6.1.2.	For emergency responders:
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.
6.2	Environmental precautions:
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.
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: Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).
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
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7.1	Precautions for safe handling
7.1.1.	Protection measures

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Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use non-sparkling tools and equipment.
Measures to prevent aerosol and dust generation:	Ensure adequate 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:	Store in a well-ventilated place, protected from sunlight, away from sources of heat and ignition, in its original, unopened and hermetically sealed packaging, away from oxidizing agents, food, feed and articles of consumption.
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	-

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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)	-	-	380 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	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m ³ (ethanol)	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)

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	2.9 mg/kg (ethanol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol)
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	no information available

8.2 Exposure controls

8.2.1. Appropriate engineering controls

<p>Substance/mixture related measures to prevent exposure during identified uses:</p>	<p>In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.</p>
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	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:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation. Use non-sparkling ventilation system. Provide appropriate personal protective equipment, safety shower and eye-wash station.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield (EN ISO 16321-1:2022, EN 166).
8.2.2.2.	Skin protection	
	Hand protection:	Use appropriate, chemical-resistant protective gloves (EN 374).
	Other skin protection:	Use appropriate protective clothing.
8.2.2.3.	Respiratory protection:	In case of normal usage and ventilation, it is not necessary. If concentration of ethyl alcohol exceeds occupational exposure limits in the air, use a self-contained breathing apparatus. For short contact and if the oxygen content of the air is greater than 18 %, use a protective gas mask with filter A (EN 14837/A1).
8.2.2.4.	Thermal hazards:	No thermal hazards known.
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

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Odour/odour threshold:	ethanol like/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
Flash point:	17 °C	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
pH:	7.0 – 8.0 (20°C)	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density:	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
9.2	Other information	
	-	

SECTION 10. Stability and reactivity

10.1	Reactivity:	See Section 10.5.
10.2	Chemical stability:	Stable within normal temperature and general work conditions.
10.3	Possibility of hazardous reactions:	See Section 10.5.
10.4	Conditions to avoid:	Keep away from heat, sparks, open flames, strong heating and ignition sources. No smoking.
10.5	Incompatible materials:	Strong oxidizing agents (inorganic strong acid, nitric acid, perchlorates, peroxy compounds, perchloric acid, permanganates etc.), alkali metals, alkali earth metals.
10.6	Hazardous decomposition products:	Carbon monoxide and carbon dioxide.

SECTION 11. Toxicological information

11.1	Information on hazard classes as defined in Regulation (EC) No 1272/2008	
	Acute toxicity:	

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Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	rabbit (ethanol)	LD ₅₀	-	>20.000 mg/l
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	>8.000 mg/l

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:	-	-	-	-	-
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:	Absorption of great quantities may cause dizziness, drunkenness, euphoria, unconsciousness and alcohol poisoning. In case of swallowing great quantities, nausea and vomiting may occur. Repeated or prolonged exposure may lead to liver cirrhosis.
Dermal exposure:	After prolonged or repeated exposure symptoms may include: defatting, dryness and cracking of skin.
Inhalation exposure:	Inhalation of great quantities may cause dizziness, euphoria and mild irritation of the mucous membranes.
Eye exposure:	May cause irritation and redness.

Repeated dose toxicity (subacute, subchronic, chronic)

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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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	-

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Chronic inhalation	No information available	No information available	-
CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)			
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 Information on other hazards:			
11.2.1. Endocrine disrupting properties:			
Based on available data, does not contain endocrine disruptors.			
11.2.2. Other informations:			
-			

SECTION 12. Ecological information						
12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	golden orf	No information available	8.140 mg/l /48 h (ethanol)	-
Crustacea:	EC ₅₀	48 hours	daphnia magna	No information available	7.800 mg/l (ethanol)	-
Algae/aquatic plants	IC ₅₀	4 days	algae	No information available	5.000 mg/l / 7d (ethanol)	-
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	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

12.3 Bioaccumulative potential

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

Value	Concentration	pH	°C	Method	Evaluation	Note
Log Pow: ~ 0.32	-	-	-	-	-	The product does not bioaccumulate

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Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
BCF: 0.66	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	-

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12.5	Results of PBT and vPvB assessment
	Based on available data, the product does not contain any PBT or vPvB substances.

12.6.	Endocrine disrupting properties
	Based on available data, does not contain endocrine disruptors.

12.7.	Other adverse effects
	Do not let the product or its residues reach sewer system, waterways and soil.

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. Unused product residues may be burnt.

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

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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
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
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:	-
	Restrictions:	-
	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>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</p>
15.2	Chemical safety assessment	
	None	

SECTION 16. Other information

16.1	Indication of changes:	-
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16.2	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
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:	<p>225 Highly flammable liquid and vapour.</p> <p>314 Causes severe skin burns and eye damage.</p> <p>335 May cause respiratory irritation.</p>
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

ANNEX: Exposure scenario resulting to chemical safety assessment
-

Trading name:	TB - FUCHSIN REAGENT				
Product code:	TBFR-OT-X**	Revision date:	23 Dec 2022	Version:	2

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

1.1	Product identifier	
	Trading name:	TB FUCHSIN REAGENT
	Chemical name:	-
	Catalogue number:	TBFR-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with TB-Stain ECO 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
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	TB FUCHSIN REAGENT
	Identification number:	-
	Authorization number:	-

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Hazard pictograms:	
	GHS02
Signal word:	Danger
Hazard statements:	H226 Flammable liquid and vapor.
Precautionary statements:	P210 Keep away from heat, hot sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
Supplemental hazard information (EU):	-

2.3 Other hazards

The product has no other known specific hazards for human or environment.

Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.

Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.

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- 0147	10 – 20 %	ethanol	Flam. Liq. 2; H225

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:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.
Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.

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	Following eye contact:	In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 10 minutes). If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Place the victim in a comfortable position. Rinse the mouth with clean water. If the victim is conscious induce vomiting. Do not give the victim anything orally, and do not induce vomiting if the victim is unconscious or suffers from convulsions.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.
	Following eye contact:	May irritate the eyes.
	Following ingestion:	Ingestion of larger quantities may affect the central nervous system.
4.3	Indication of any immediate medical attention and special treatment needed	
	If larger quantities have entered the body, obtain medical treatment (gastric lavage, activated carbon).	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Extinguishing powder, alcohol-resistant foam, water, carbon-dioxide.
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Highly flammable liquid and vapour. In case of fire, smoke, and other combustion products (carbon monoxide, carbon dioxide) may be formed, the inhalation of such combustion products can have serious adverse effects on health. Vapours may form an explosive mix with air. Vapours may be ignited by open flames, sparks, electrical equipment, or static charge. Vapours may travel to great distances, ignite in contact with ignition sources and flash back to the primer source (container). Vapours of ethyl alcohol mix greatly with air and may form an explosive mixture. Air containing 3.3 – 19 % ethyl alcohol vapours may explode in contact with ignition sources. Diluting the mixture with large amounts of water results in the loss of its flammability (around 10 % concentration of ethyl alcohol).
5.3	Advice for firefighters	
	Wear full protective clothing and self-contained breathing apparatus. Cool the fire affected containers with water spray. Use water spray to dissipate alcohol vapours.	
5.4	Additional information	
	-	

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SECTION 6. Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.	
6.2	Environmental precautions:	
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.	
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:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).
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	

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Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use non-sparkling tools and equipment.
Measures to prevent aerosol and dust generation:	Ensure adequate 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:	Store in a well-ventilated place, protected from sunlight, away from sources of heat and ignition, in its original, unopened and hermetically sealed packaging, away from oxidizing agents, food, feed and articles of consumption.
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/-	-
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	1900 mg/m ³ (ethanol)	-	-	380 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	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m ³ (ethanol)	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)

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	2.9 mg/kg (ethanol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol)
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:	In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.
Structural measures to prevent exposure:	In accordance with Section 7.

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	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation. Use non-sparking ventilation system. Provide appropriate personal protective equipment, safety shower and eye-wash station.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield (EN ISO 16321-1:2022, EN 166).
8.2.2.2.	Skin protection	
	Hand protection:	Use appropriate, chemical-resistant protective gloves (EN 374).
	Other skin protection:	Use appropriate protective clothing.
8.2.2.3.	Respiratory protection:	In case of normal usage and ventilation, it is not necessary. If concentration of ethyl alcohol exceeds occupational exposure limits in the air, use a self-contained breathing apparatus. For short contact and if the oxygen content of the air is greater than 18 %, use a protective gas mask with filter A (EN 14837/A1).
8.2.2.4.	Thermal hazards:	No thermal hazards known.
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 violet	No information available
	Odour/odour threshold:	ethanol like/no information available	No information available
	Melting point / freezing point:	No information available	No information available

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	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	47 °C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

SECTION 10. Stability and reactivity

10.1	Reactivity:	See Section 10.5.
10.2	Chemical stability:	Stable within normal temperature and general work conditions.
10.3	Possibility of hazardous reactions:	See Section 10.5.
10.4	Conditions to avoid:	Keep away from heat, sparks, open flames, strong heating and ignition sources. No smoking.
10.5	Incompatible materials:	Strong oxidizing agents (inorganic strong acid, nitric acid, perchlorates, peroxy compounds, perchloric acid, permanganates etc.), alkali metals, alkali earth metals.
10.6	Hazardous decomposition products:	Carbon monoxide and carbon dioxide.

SECTION 11. Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008					
Acute toxicity:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	rabbit (ethanol)	LD ₅₀	-	>20.000 mg/l

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Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	>8.000 mg/l	
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:	-	-	-	-	-	
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:	Absorption of great quantities may cause dizziness, drunkenness, euphoria, unconsciousness and alcohol poisoning. In case of swallowing great quantities, nausea and vomiting may occur. Repeated or prolonged exposure may lead to liver cirrhosis.					
Dermal exposure:	After prolonged or repeated exposure symptoms may include: defatting, dryness and cracking of skin.					
Inhalation exposure:	Inhalation of great quantities may cause dizziness, euphoria and mild irritation of the mucous membranes.					
Eye exposure:	May cause irritation and redness.					
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:	Based on available data, the classification criteria are not met.
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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 Information on other hazards:	
11.2.1. Endocrine disrupting properties:	
Based on available data, does not contain endocrine disruptors.	
11.2.2. Other informations:	
-	

SECTION 12. Ecological information						
12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	golden orf	No information available	8.140 mg/l /48 h (ethanol)	-
Crustacea:	EC ₅₀	48 hours	daphnia magna	No information available	7.800 mg/l (ethanol)	-
Algae/aquatic plants	IC ₅₀	4 days	algae	No information available	5.000 mg/l / 7d (ethanol)	-
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	-

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Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

12.3 Bioaccumulative potential

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

Value	Concentration	pH	°C	Method	Evaluation	Note
-	-	-	-	-	-	-

Bioconcentration factor (BCF)

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

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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

Based on available data, the product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Based on available data, does not contain endocrine disruptors.

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12.7.	Other adverse effects
	Do not let the product or its residues reach sewer system, waterways and soil.

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. Unused product residues may be burnt.

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:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	1170

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UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Further information:	<p>ADR: Special provision 144 - Aqueous solution containing 24% or less alcohol volume, not subjected to classification.</p> <p>IATA: Special provision A58 - Aqueous solution containing 24% or less alcohol volume, not subjected to classification.</p>
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SECTION 15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Trading name:	TB - FUCHSIN REAGENT				
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	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -
	<p>Other EU regulations:</p> <p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)
	<p>National legislation:</p> <p>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</p>
15.2	Chemical safety assessment
	None

SECTION 16. Other information

16.1	Indication of changes:	-
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Trading name:	TB - FUCHSIN REAGENT				
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16.2	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
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: 225	Highly flammable liquid and vapor.
	226	Flammable liquid and vapor.
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

ANNEX: Exposure scenario resulting to chemical safety assessment
-

Trading name:	METHYLENE BLUE LOEFFLER'S REAGENT				
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

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

1.1	Product identifier	
	Trading name:	METHYLENE BLUE LOEFFLER'S REAGENT
	Chemical name:	-
	Catalogue number:	MBL-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For staining in microbiology and histology.
	Uses advised against:	Only the identified uses are advised. Unsuitable for human consumption.
	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
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	METHYLENE BLUE LOEFFLER'S REAGENT
	Identification number:	-
	Authorization number:	-

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Hazard pictograms:	
	GHS02
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statements:	P210 Keep away from heat, hot sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
Supplemental hazard information (EU):	-

2.3	Other hazards
	<p>The product has no other known specific hazards for human or environment.</p> <p>Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.</p> <p>Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.</p>

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- 0147	10 – 20 %	ethanol	Flam. Liq. 2; H225

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:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.
Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.

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	Following eye contact:	In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 10 minutes). If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Place the victim in a comfortable position. Rinse the mouth with clean water. If the victim is conscious induce vomiting. Do not give the victim anything orally, and do not induce vomiting if the victim is unconscious or suffers from convulsions.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.
	Following eye contact:	May irritate the eyes.
	Following ingestion:	Ingestion of larger quantities may affect the central nervous system.
4.3	Indication of any immediate medical attention and special treatment needed	
	If larger quantities have entered the body, obtain medical treatment (gastric lavage, activated carbon).	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Extinguishing powder, alcohol-resistant foam, water, carbon-dioxide.
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Highly flammable liquid and vapour. In case of fire, smoke, and other combustion products (carbon monoxide, carbon dioxide) may be formed, the inhalation of such combustion products can have serious adverse effects on health. Vapours may form an explosive mix with air. Vapours may be ignited by open flames, sparks, electrical equipment, or static charge. Vapours may travel to great distances, ignite in contact with ignition sources and flash back to the primer source (container). Vapours of ethyl alcohol mix greatly with air and may form an explosive mixture. Air containing 3.3 – 19 % ethyl alcohol vapours may explode in contact with ignition sources. Diluting the mixture with large amounts of water results in the loss of its flammability (around 10 % concentration of ethyl alcohol).
5.3	Advice for firefighters	
	Wear full protective clothing and self-contained breathing apparatus. Cool the fire affected containers with water spray. Use water spray to dissipate alcohol vapours.	
5.4	Additional information	
	-	

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SECTION 6. Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.	
6.2	Environmental precautions:	
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.	
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:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).
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	

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Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use non-sparkling tools and equipment.
Measures to prevent aerosol and dust generation:	Ensure adequate 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:	Store in a well-ventilated place, protected from sunlight, away from sources of heat and ignition, in its original, unopened and hermetically sealed packaging, away from oxidizing agents, food, feed and articles of consumption.
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/-	-
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	1900 mg/m ³ (ethanol)	-	-	380 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	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m ³ (ethanol)	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)

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	2.9 mg/kg (ethanol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol)
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	no information available

8.2 Exposure controls

8.2.1. Appropriate engineering controls

<p>Substance/mixture related measures to prevent exposure during identified uses:</p>	<p>In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.</p>
<p>Structural measures to prevent exposure:</p>	<p>In accordance with Section 7.</p>

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	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation. Use non-sparking ventilation system. Provide appropriate personal protective equipment, safety shower and eye-wash station.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield (EN ISO 16321-1:2022, EN 166).
8.2.2.2.	Skin protection	
	Hand protection:	Use appropriate, chemical-resistant protective gloves (EN 374).
	Other skin protection:	Use appropriate protective clothing.
8.2.2.3.	Respiratory protection:	In case of normal usage and ventilation, it is not necessary. If concentration of ethyl alcohol exceeds occupational exposure limits in the air, use a self-contained breathing apparatus. For short contact and if the oxygen content of the air is greater than 18 %, use a protective gas mask with filter A (EN 14837/A1).
8.2.2.4.	Thermal hazards:	No thermal hazards known.
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:	blue	No information available
	Odour/odour threshold:	ethanol like/no information available	No information available
	Melting point / freezing point:	No information available	No information available

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	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	40 °C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	7.0 – 8.0 (20°C)	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

SECTION 10. Stability and reactivity

10.1	Reactivity:	See Section 10.5.
10.2	Chemical stability:	Stable within normal temperature and general work conditions.
10.3	Possibility of hazardous reactions:	See Section 10.5.
10.4	Conditions to avoid:	Keep away from heat, sparks, open flames, strong heating and ignition sources. No smoking.
10.5	Incompatible materials:	Strong oxidizing agents (inorganic strong acid, nitric acid, perchlorates, peroxy compounds, perchloric acid, permanganates etc.), alkali metals, alkali earth metals.
10.6	Hazardous decomposition products:	Carbon monoxide and carbon dioxide.

SECTION 11. Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008					
Acute toxicity:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	rabbit (ethanol)	LD ₅₀	-	>20.000 mg/l

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Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	>8.000 mg/l
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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:	No information available.
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Irritation and corrosion

	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:	Absorption of great quantities may cause dizziness, drunkenness, euphoria, unconsciousness and alcohol poisoning. In case of swallowing great quantities, nausea and vomiting may occur. Repeated or prolonged exposure may lead to liver cirrhosis.
Dermal exposure:	After prolonged or repeated exposure symptoms may include: defatting, dryness and cracking of skin.
Inhalation exposure:	Inhalation of great quantities may cause dizziness, euphoria and mild irritation of the mucous membranes.
Eye exposure:	May cause irritation and redness.

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:	Based on available data, the classification criteria are not met.
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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 Information on other hazards:	
11.2.1. Endocrine disrupting properties:	
Based on available data, does not contain endocrine disruptors.	
11.2.2. Other informations:	
-	

SECTION 12. Ecological information						
12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	golden orf	No information available	8.140 mg/l /48 h (ethanol)	-
Crustacea:	EC ₅₀	48 hours	daphnia magna	No information available	7.800 mg/l (ethanol)	-
Algae/aquatic plants	IC ₅₀	4 days	algae	No information available	5.000 mg/l / 7d (ethanol)	-
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	-

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Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

12.3 Bioaccumulative potential

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

Value	Concentration	pH	°C	Method	Evaluation	Note
Log Pow: ~ 0.32	-	-	-	-	-	The product does not bioaccumulate

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
BCF: 0.66	No information available	No information available	No information available	-

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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

Based on available data, the product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Based on available data, does not contain endocrine disruptors.

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12.7.	Other adverse effects
	Do not let the product or its residues reach sewer system, waterways and soil.

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. Unused product residues may be burnt.

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:	III
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	1170

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UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

Further information:	<p>ADR: Special Provision 144 – An aqueous solution containing 24% or less alcohol by volume is not subject to classification.</p> <p>IATA: Special Provision A58 - An aqueous solution containing 24% or less alcohol by volume is not subject to classification.</p>
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SECTION 15. Regulatory information

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture
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Trading name:	METHYLENE BLUE LOEFFLER'S REAGENT				
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>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</p>
15.2	Chemical safety assessment	
	None	

SECTION 16. Other information

16.1	Indication of changes:	-
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Trading name:	METHYLENE BLUE LOEFFLER'S REAGENT				
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

16.2	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	Manufacturer's MSDS file.
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:	225 226
		Highly flammable liquid and vapour. Flammable liquid and vapour.
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

ANNEX: Exposure scenario resulting to chemical safety assessment
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