

TB-STAIN FLUORESCENT KIT

The kit contains:

TB Auramine-Rhodamine reagent

TB Decolorizer Fluorescent

TB Permanganate reagent

Trade name:	TB AURAMINE-RHODAMINE REAGENT		
Product code:	TBA-OT-X**	Date of compilation:	29 December 2022
		Version:	5


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

1.1.	Product identifier	
	Trade name:	TB AURAMINE-RHODAMINE REAGENT
	Chemical name:	-
	Catalogue number:	TBA-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in TB-Stain Fluorescent 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 numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification

2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No. 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statement*:
	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 AURAMINE-RHODAMINE REAGENT
	Identification number:	-

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Authorisation number:	-
Hazard pictograms:	 GHS02
Signal word:	Danger
Hazard statement:	H225 Highly flammable liquid and vapor.
Precautionary statement:	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

Endocrine Disrupting Properties:

No known endocrine disrupting properties

Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.

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	75 – 95 %	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:	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 all contaminated clothes/footwear. Thoroughly wash with water for at least 15 minutes.	

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	Following eye contact:	Rinse the eyes using mild jet of clean water for at least 20 minutes with the eyelids held wide open.
	Following swallowing:	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 swallowing:	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	
	No information available	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, alcohol-resistant foam, CO2 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 byproducts of fire:	Incomplete combustion of the product.
5.3.	Advice for firefighters	
	Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing).	
5.4.	Additional information	
	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).

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	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:	
	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112). 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	

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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.
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/-	No information available
Substance: -				
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

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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 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:	Do not eat, drink or smoke in the workspace. Use personal protective equipment.
Structural measures to prevent exposure:	No information available
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	See Section 7.2

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection:	Safety glasses 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:	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

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	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:	red	no information available
	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:	13°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

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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
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SECTION 10.: Stability and reactivity

10.1.	Reactivity:	The product is stable under normal working and storage conditions.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.
10.4.	Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5.	Incompatible materials:	Oxidants, acids, alkali metals.
10.6.	Hazardous decomposition products:	Non-degradable if used in the described manner.

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	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	LD ₅₀	-	7.060 mg/kg (ethanol)
Dermal:	No information available	rabbit	LD ₅₀	-	>20.000 mg/kg (ethanol)
Inhalation:	No information available	rat	LC ₅₀	4 h (ethanol)	20.000 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	-

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Aspiration hazard:	No information available
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Irritation and corrosion					
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	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	No information available	No information available	No information available	No information available	-
Serious eye damage/irritation	No information available	No information available	No information available	No information available	-

Sensitization					
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Skin sensitization:	No information available				
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Respiratory sensitization:	No information available				
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Symptoms related to the physical, chemical and toxicological characteristics					
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Oral exposure:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.				
Dermal exposure:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.				
Inhalation exposure:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.				
Eye exposure:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.				

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	-

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Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

Specific target organ toxicity - repeated exposure (STOT-RE):

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)

Carcinogenicity:	No information available
Mutagenicity <i>in-vitro</i> :	No information available
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	No information available
Germ cell mutagenicity :	No information available
Reproductive toxicity:	No information available

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Summary of evaluation of the CMR properties:		No information available
11.2. Information on other hazards:		
11.2.1. Endocrine disrupting properties:		
No known endocrine disrupting properties that affect human health.		
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	Fish	No information available	8.140 mg/l (ethanol)	-
Crustacea:	EC ₅₀	48 hours	Daphnia magna	No information available	7.800 mg/l (ethanol)	-
Algae/aquatic plants:	IC ₅₀	72 hours	algae	No information available	5.000 mg/l (ethanol)	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	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
-	-	-	-	-

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 (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	-

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12.4. Mobility in soil						
Known or predicted distribution in environmental compartments:						
No information available						
Surface tension:						
	Value	°C	Concentration	Method	Note	
	No information available	No information available	No information available	No information available	-	
Adsorption / desorption						
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-Water	No information available	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	No information available	-
Soil-Air	No information available	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.						
12.7. Other adverse effects						
No adverse effects are expected.						
SECTION 13. Disposal considerations						
13.1. Waste treatment methods						
13.1.1. Product/Packaging disposal:						
Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.						

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13.1.2.	Waste codes/waste designations according to Low:
	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	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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
Environmental hazards:	No information available
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3

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Packing group:	II
Environmental hazards:	No information available
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
Environmental hazards:	No information available
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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	
	Authorisation and/or restrictions on use	
	Authorisations:	-
	Restrictions:	-

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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>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:	-
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>

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16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H: 225	Highly flammable liquid and vapor.
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment
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Trading name:	TB DECOLORIZER FLUORESCENT				
Product code:	TBF-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 FLUORESCENT
	Chemical name:	-
	Catalogue number:	TBF-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in TB-Stain Fluorescent and TB-Stain Auramine O kits.
	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
	Eye Irr. 2	H319
	STOT SE 3	H336
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 FLUORESCENT
	Identification number:	-

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Authorization number:	-
Hazard pictograms:	  GHS02 GHS07
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness
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. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental hazard information (EU):	-

2.3 Other hazards
Endocrine Disrupting Properties:

No known endocrine disrupting properties

Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.

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)
67-63-0/ 200-661-7/ 603-117-00-0	01-2119457558-25- XXXX	≥60%	propan-2-ol	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336
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

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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.
	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.	

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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 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
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7.1	Precautions for safe handling
7.1.1.	Protection measures

Trading name:	TB DECOLORIZER FLUORESCENT				
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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.
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	
Propan-2-ol	67-63-0	400/500	999/1250	-
Hydrogen chloride	7647-01-0	5/10	8/15	-
Substance name:	-			
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	-	-	-	26 mg/kg (propan-2-ol)
Inhalation	-	-	-	500 mg/m ³ (propan-2-ol)
Dermal	-	-	-	888 mg/kg (propan-2-ol)

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	26 mg/kg (propan-2-ol)
Inhalation	-	-	-	89 mg/m ³ (propan-2-ol)
Dermal	-	-	-	319 mg/kg (propan-2-ol)

PNEC

Environmental protection target	PNEC
Fresh water	140.9 mg/l (propan-2-ol)
Freshwater sediments	552 mg/kg (propan-2-ol)
Marine water	140.9 mg/l (propan-2-ol)
Marine sediments	552 mg/kg (propan-2-ol)
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	28 mg/kg (propan-2-ol)
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.

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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.
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/odour threshold:	biting/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

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Flammability:	No information available	No information available
Initial boiling point and boiling range:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
Flash point:	18 °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 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 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	LD ₅₀	-	5.840 mg/kg (propan-2-ol)
Dermal:	-	rabbit	-	-	12.800 mg/kg (propan-2-ol)

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Inhalation:	-	rat	LC ₅₀	4 h	37.5 mg/l (propan-2-ol) 4.74 mg/l (hydrochloric acid)
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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	may cause drowsiness or dizziness

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:	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	-

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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	-

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.
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.

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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:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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	No information available	No information available	100-1,000 mg/l (2-propanol)	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	>1,000 mg/l (2-propanol)	-
Algae/aquatic plants	IC ₅₀	4 days	No information available	No information available	>1,000 mg/l (2-propanol)	-
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	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	information available	No information available	No information available	No information available	-
Water-air	No information available	information available	No information available	No information available	No information available	-
Soil-air	No information available	information available	No information available	No information available	No information available	-

12.5 Results of PBT and vPvB assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

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The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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:

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:	1219
UN proper shipping name:	Isopropanol
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-

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Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	1219
UN proper shipping name:	Isopropanol
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1219
UN proper shipping name:	Isopropanol
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	1219
UN proper shipping name:	Isopropanol
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:	1219
UN proper shipping name:	Isopropanol
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

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	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>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:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment
	None

SECTION 16. Other information

16.1	Indication of changes:	-
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16.2	Abbreviations and acronyms:	<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: H225 H314 H319 H331 H336	<p>Highly flammable liquid and vapor.</p> <p>Causes severe skin burns and eye damage.</p> <p>Causes serious eye irritation</p> <p>Toxic if inhaled.</p> <p>May cause drowsiness or dizziness.</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

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Trading name:	TB PERMANGANATE REAGENT				
Product code:	TBP-OT-X**	Date of compilation:	21 Dec 2022	Version:	6

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

1.1	Product identifier	
	Trading name:	TB PERMANGANATE REAGENT
	Chemical name:	-
	Catalogue number:	TBP-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Counterstain for use in TB-Stain Fluorescent kit and TB-Stain Auramine O kits.
	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*:
	Aquatic Chronic 3	H412
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	TB PERMANGANATE REAGENT
	Identification number:	-
	Authorization number:	-

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Hazard pictograms:	-
Signal word:	-
Hazard statements:	H412 Harmful to aquatic life with long lasting effects.
Precautionary statements:	P273 Avoid release to the environment P501 Dispose of contents/container in accordance with local regulations.
Supplemental hazard information (EU):	-

2.3 Other hazards

Endocrine Disrupting Properties:

No known endocrine disrupting properties

Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.

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)
7722-64-7/ 231-760-3/ 025-002-00-9	-	<1%	potassium permanganate	Ox. Sol. 2; H272 Acute Tox. 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 Repr. 2; H361d

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 oral cavity, drink 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.

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	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:	Water spray, foam, dry powder, CO ₂
	Unsuitable extinguishing media:	No information available
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	May product toxic fumes of carbon monoxide if burning.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	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.
	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:	

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	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 or clay barriers.
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:	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.
	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 at temperatures ranging from 15 to 25 °C.
	Packaging materials:	Manufacturer's original packaging. Avoid metal containers.
	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	
Potassium permanganate	7722-64-7	-	0.5	-

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	-	-	-	0.218 mg/m ³ (potassium permanganate)
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	0.06 µg/l (potassium permanganate)
Freshwater sediments	no information available
Marine water	no information available

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Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	1.64 mg/l (potassium permanganate)
Soil (agricultural)	no information available
Air	no information available

8.2	Exposure controls
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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:	Protective nitrile gloves, >0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Not required under normal conditions of use. Use suitable respiratory protective device when high concentrations are present.
8.2.2.4.	Thermal hazards:	No information available

8.2.3.	Environmental exposure controls
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	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.

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Technical measures to prevent exposure:	See Section 6
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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 purple	No information available
	Odour/odour threshold:	odourless/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:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	6.1 – 6.9	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 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.

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10.5	Incompatible materials:	Reducing agents, sulfuric acid, flammables, metals and reactive organic materials.
10.6	Hazardous decomposition products:	Carbon oxides (CO, CO ₂). Oxygen, oxides of potassium and manganese.

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	LD ₅₀	-	750 mg/kg (potassium permanganate)
Dermal:	-	-	-	-	-
Inhalation:	-	-	-	-	-

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:	-
Respiratory sensitization:	-

Symptoms related to the physical, chemical and toxicological characteristics

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

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	-

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Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
Carcinogenicity:	No information available.
Mutagenicity <i>in vitro</i> :	No information available.
Genotoxicity:	No information available.
Mutagenicity <i>in vivo</i> :	No information available.
Germ cell mutagenicity:	No information available.
Reproductive toxicity:	No information available.
Summary of evaluation of the CMR properties:	
No information available.	

11.2	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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	<i>Oncorhynchus mykiss</i> (rainbow trout)	-	-	0.3 – 0.6 mg/l (potassium permanganate)

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Crustacea:	EC ₅₀	48 hours	<i>Daphnia magna</i> (Water flea)	-	-	0.084 mg/l (potassium permanganate)
Algae/aquatic plants	IC ₅₀	4 days	-	-	-	-
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
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})

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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	-

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	-

Trading name:	TB PERMANGANATE REAGENT				
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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

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.6. Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7. 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:

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.

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13.1.6.	Relevant Community provisions:
	-

SECTION 14 TRANSPORT INFORMATION

Transporting/shipment by road (ADR)	
UN number:	3082
UN proper shipping name:	Environmentally hazardous substance, liquid, n.o.s. (potassium permanganate)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	3082
UN proper shipping name:	Environmentally hazardous substance, liquid, n.o.s. (potassium permanganate)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	3082
UN proper shipping name:	Environmentally hazardous substance, liquid, n.o.s. (potassium permanganate)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	3082
UN proper shipping name:	Environmentally hazardous substance, liquid, n.o.s. (potassium permanganate)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-

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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:	3082
UN proper shipping name:	Environmentally hazardous substance, liquid, n.o.s. (potassium permanganate)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Further information: Packages smaller than or equal to 5 kg / L, not dangerous goods of Class 9.	

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>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)	

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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:	<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)	
	272	May intensify fire; oxidiser.
	302	Harmful if swallowed.
H:	361d	Suspected of damaging the unborn child.
	400	Very toxic to aquatic life.
	410	Very toxic to aquatic life with long lasting effects.
	412	Harmful to aquatic life with long lasting effects
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>

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ANNEX: Exposure scenario resulting to chemical safety assessment

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