

TB-STAIN ECO KIT

The kit contains:

TB Fuchsin reagent
TB Decolorizer
Methylene Blue Loeffler reagent



SAFETY DATA SHEET According to Regulation (EC) No. 1907/2006

amended by Regulation (EU) No. 2020/878

Page 1 of 17

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

SECTI	ON 1: Identification of	the substance	e/mixture	e and of the company/undertaking		
1.1	Product identifier					
	Trading name:	TB DECOLO	RIZER			
	Chemical name:	-				
	Catalogue number:	TBD-OT-X*	*			
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against		
	Uses:		For use	in TB-Stain Cold and TB-Stain Hot kit.		
	Uses advised against:		Only the	e identified uses are advised.		
	Reason why uses advised against: de			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 shee	t		
	Supplier:		BioGnost Ltd.			
	Address:		Medjugorska 59, Zagreb			
	Telephone number:		+385 1 2	2409997		
	Telefax.:		+385 1 2	2404039		
	e-mail of competent p	erson:	msds@b	<u>oiognost.hr</u>		
	National contact:		-			
1.4	Emergency telephone number					
	National Protection ar	nd Rescue Dire	ectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	ECTION 2. Hazards identification				
2.1	Classification of the substance or mixture				
2.1.1	Classification according to I	Regulation (EC) No 1	1272/2008 (CLP)		
	Hazard class and ca	tegory code:	Hazard statements*:		
	Flam. Liq. 2		H225		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Haza	ard-statements: see S	SECTION 16		
2.2	Label elements				
	Product identification:	TB DECOLORIZ	ZER		
	Identification number: -				
	Authorization number:	-			



Page 2 of 17

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

	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.		
	Supplemetal 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	y: Based on available data, does not contain endocrine disruptors.		

SECTION 3. Co	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		

SECTIO	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.			



Page 3 of 17

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

	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 ef	fects, both acute and delayed
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.
i		
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.
	Following skin contact: Following eye contact:	
		dryness of the skin.
4.3	Following eye contact: Following ingestion:	dryness of the skin. May irritate the eyes.

SECTI	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 su	ubstance 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 s water spray. Use water spray to dis	relf-contained breathing apparatus. Cool the fire affected containers with ssipate alcohol vapours.			



Page 4 of 17

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

5.4	Additional information
	-

	ON 6. Accidental release measu		
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:		
	ventilation. Vapours may accun	nd clothing and inhaling gases, vapours and aerosols. Ensure adequate nulate at floor level in low and confined spaces. Remove all heat, ignition thines. Ignition spark arrestor must not be operated in the danger area. Use 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 conta	ainment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.	
6.3.2.	Cleaning up:	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 o	n safe handling.	
	See Section 8 for information on personal protection equipment.		
	See Section 6 for information 6	become become education	

	SECTION 7. Handling and storage		
	7.1	Precautions for safe handling	
I	7.1.1.	Protection measures	



Page 5 of 17

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

	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 generatio	n:	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. The	oroughly wa	sh 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:	Manufactı	Manufacturer's original packaging.		
	Requirements for storage rooms and vessels: Keep away from food and drink. Keep the contain tightly closed.				
	Advices for storage equipment:		ge must be made of hard material; floors must nt to chemicals. There must be no drain that eads into sewage system. Secure proper n.		
	Further information on storage conditions:	and do r	ace the unused material in the storage room not use empty containers for storing other . Do not store with incompatible materials (see 0).		
7.3	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	_			

SECTION 8. Exposure controls/personal protection					
8.1 Control parameters	8.1 Control parameters				
Substance	CAS No	· ·	exposure limit term values	Biological limit values	
		ppm	mg/m³		
Ethanol	64-17-5	1000/-	1900/-	-	
Hydrogen chloride	7647-01-0	5/10	8/15	-	



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

Page 6 of 17

Trading na	me:	TB DECOLORIZER						
Product co	de:	TBD-OT-	-X**	Revisi	on date:	21 Dec 2022	Version: 5	
				:			1	
Substance r	name:	-						
EC No:		-	CAS No	-				
DNEL								
				In	dustrial			
Route of		Acu	te	Acute		Chronic	Chronic	
exposure:		effect	local	effect systemi	с	effect local	effect systemic	
Oral		-		-	-		-	
Inhalation		1900 mg, (ethanol)	/m³	-	-		380 mg/m³ (ethanol)	
Dermal		-		-	-		343 mg/kg (ethanol)	
Critical phys	sical para	meters: s	olubility,	flammability, co	rrosivity:	-		
				Co	nsumer	·		
Route of		Ac	ute	Acute		Chronic	Chronic	
exposure:		effec	t local	effect systemi	С	effect local	effect systemic	
Oral		-		-	-		87 mg/kg bw/day (ethanol)	
Inhalation		950 mg (ethan	-	-	-		114 mg/m³ (ethanol)	
Dermal		-		-	-		206 mg/kg (ethanol)	
PNEC								
Environmen	ital prote	ction targ	jet		PNEC			
Fresh water					0.96 mg/	'l (ethanol)		
Freshwater	sediment	ts			3.6 mg/k	g (ethanol)		
Marine wate	er				0.79 mg/l (ethanol)			
Marine sedi	ments				2.9 mg/kg (ethanol)			
Food chain					380-720 mg/kg (ethanol)			
Microorgan	isms in s	ewage tre	eatment		580 mg/l (ethanol)			
Soil (agricul	tural)				0.63 mg/kg (ethanol)			
Air					no information available			
8.2	Exposur	re control	S					
8.2.1.	Approp	riate engi	neering o	controls				
		ubstance/mixture related measures to revent exposure during identified uses:		concentr concentr existing	ation limit it is the ation levels down to	aterial with no controlled e employer's duty to keep o a minimum achievable by ological means, where the o harm to workers.		



Page 7 of 17

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

	Structural measures to prevent exposure:		In accordance with Section 7.		
	Organisational measures to preve exposure:	nt	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent exp	oosure:	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.	FVE and tace protection.		propriate, chemical-proof protective glasses/face shield (EN 321-1:2022, EN 166).		
8.2.2.2.	Skin protection				
	Hand protection:	Use ap	propriate, chemical-resistant protective gloves (EN 374).		
	Other skin protection:	Use appropriate protective clothing.			
8.2.2.3.	Respiratory protection:	concer in the contac	e of normal usage and ventilation, it is not necessary. If stration of ethyl alcohol exceeds occupational exposure limits air, use a self-contained breathing apparatus. For short and if the oxygen content of the air is greater than 18 %, use ective gas mask with filter A (EN 14837/A1).		
8.2.2.4.	Thermal hazards:	No the	rmal hazards known.		
8.2.3.	Environmental exposure controls				
	Substance/mixture related measures to prevent exposure:	See Se	ction 6		
	Structural measures to prevent exposure:	Use mo	odern equipment.		
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.		
	Technical measures to prevent exposure:	See Section 6			

SECT	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	



Page 8 of 17

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

	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
).2	Other information		
	-		

SECTIO	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	SECTION 11. Toxicological information					
11.1	Information on hazard classes as defined in Regulation (EC) No 1272/2008					
	Acute toxicity:					



Page 9 of 17

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

Product code:	TBD-OT-X** Revision date: 21 Dec 2022		2022	V	ersion: 5		
Route of exposure:	Method	Species	Dose LD ₅₀ /		Exposure tir	me	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 ta	rget organ to	xicity – single exposi	ure (STOT SE):				
3 7	S	pecific effects		Target org	an		Note
Oral:	No informa	tion available	No info	rmation ava	ilable	-	
Dermal:	No informa	tion available	No info	rmation ava	ilable	_	
Inhalation:	No informa	tion available	No info	rmation ava	ilable	_	
Aspiration	hazard:	No	information a	vailable.			
Irritation a	nd corrosion				:		
	Ехро	osure time	Species	Evaluation	Method		Note
Skin corrosion/irritation:	-	-		-	-	-	
Serious eye damage/irritation	-	-		-	-	-	
Sensitizatio	on						
Skin sensitization:		information availab	ole.				
Respiratory sensitiz		information availab					
Symptoms	related to the	e physical, chemical	and toxicolog	ical characte	eristics		
		on of great qua	•				•
Oral exposure:		ousness and alcohol may occur. Repeate			5 5	•	
Dermal exposure:	After pro	olonged or repeate of skin.	d exposure s	ymptoms m	nay include:	defatt	ing, dryness an
Inhalation exposure	Inhalation membrar	n of great quantities nes.	may cause diz	ziness, euph	oria and mild	l irritat	ion of the mucou
_							

Repeated dose toxicity (subacute, subchronic, chronic)

May cause irritation and redness.

Eye exposure:



Page 10 of 17

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

	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	-				



Page 11 of 17

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

Chronic inha	lation No	information	available	N	o information available	-		
CMI	R effects (carcino	genicity; mu	utagenicity;	reproductive toxi	city)			
Card	cinogenicity:		В	ased on available	data, the classification of	criteria are not met.		
Mut	tagenicity <i>in vitro</i>):	В	ased on available	data, the classification o	criteria are not met.		
Gen	otoxicity:		В	ased on available	data, the classification of	criteria are not met.		
Mut	tagenicity <i>in vivo</i> :	•	В	ased on available	data, the classification of	criteria are not met.		
Geri	m cell mutagenio	city:	В	ased on available	data, the classification of	criteria are not met.		
Rep	Reproductive toxicity:			Based on available data, the classification criteria are not met.				
	nmary of eval perties:	uation of	the CMF	Based on ava met.	llable data, the classific	ation criteria are not		
11.2 Info	rmation on othe	r hazards:						
11.2.1. End	ocrine disrupting	properties:						
	ed on available ocrine disruptors		not contair	1				
11.2.2. Oth	er 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			



Page 12 of 17

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

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	-	-	-	-	-	-

Abioti	c 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	-

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

12.3	Bioacc	ioaccumulative potential					
	Octano	ol-water partition o	coefficien	t (log Ko	w)		
Va	lue	Concentration	рН	°C	Method	Evaluation	Note
Log Pov 0.32	W: ~	-	-	-	-	-	The product does not bioaccumulate



Page 13 of 17

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

rioduc	it code.		7-01-X					-			
	Riocons	antratio	on factor (BCF)								
		ziiii aliO			k /	loth od		F = 1	luatio :-	**	Note
V	/alue		Species			lethod 			luation 		Note
BCF: 0.6	56	No avai	inform lable	ation	No info			No infor		-	
	Chronic	ecotoxi	city								
	Value		Dose	1	osure me	Specie	es	Metho	d	Evaluation	Note
Chronic	toxicity o	n fish	LC ₅₀	No infori availa	mation able	No informat available		No informat available	1	o formation ailable	-
	toxicity o ea (<i>Daphn</i>		EC ₅₀	No infori availa	mation able	No informat available		No informat available		o formation vailable	-
12.4		or predi	cted distributi available	on in e	environme	ental com	npartr	ments:			
	Surface	tension	•								
	Value	e	°C	C	oncentrat	ion		Method			Note
	No informat		No	No							
	available		information available		informat ilable		o info vailab	ormation le		-	
	available									-	
		2 (-	
Transpo	Adsorpti	ion / de	available	ava		a	vailab		Met	thod	Note
Transpo Soil-wa	Adsorpti	ion / de	esorption coefficient y's constant information	lo	og Kow oformatio	Evap	oratic	on rate ation	Met No infor available	thod	Note -
	Adsorpti	ion / de A/D Henry	esorption coefficient y's constant information ole information	lo No ir availa	og Kow oformationable	Evap n No ir	oratic oformable	on rate ation	No infor	thod mation	Note -



Page 14 of 17

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

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.
SECTIO	N 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. Unused product residues may be
	burnt.
13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.
SECTIO	N 14 TRANSPORT INFORMATION
	Transporting/shipment by road (ADR)
UN num	
	per shipping name: Ethanol solution
2 p.or	



Environmentally hazardous:

Special precautions for user:

Further information:

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

Page 15 of 17

Trading name:		TB DECOLORIZER					
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5		
T	1()	2					
Transport hazard c	lass(es):	3					
Packing group:		II					
Environmentally ha		-					
Special precautions		-					
<u> </u>	ing/shipment by rail (R	T					
UN number:		1170					
UN proper shippin		Ethanol solution					
Transport hazard c	lass(es):	3					
Packing group:							
Environmentally ha		-					
Special precautions		-					
· · · · · · · · · · · · · · · · · · ·	terway transport (ADN)						
UN number:		1170					
UN proper shippin		Ethanol solution					
Transport hazard c	lass(es):	3					
Packing group:		II					
Environmentally ha		-					
Special precautions		-					
i	ing/shipment by sea (IN						
UN number:		1170					
UN proper shippin	g name:	Ethanol solution					
Transport hazard c	lass(es):	3					
Packing group:		II					
Environmentally ha	azardous:	-					
Special precautions	s for user:	-					
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:		-					
Transport	ing/shipment by air (IC	AO-TI/IATA-DGR)					
UN number:		1170					
UN proper shippin	g name:	Ethanol solution					
Transport hazard c	lass(es):	3					
Packing group:		11					

-



Page 16 of 17

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

15.1	Safety, health and enviror	nmental regulations/legislation specific for the substance or mixture
	EU regulations	
	Authorization and/or rest	rictions of use
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	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 (EC) 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; 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; 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; 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; 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).
		REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	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 assessme	ent
	None	

SECTION 16. Other information	
16.1 Indication of changes:	-



SAFETY DATA SHEET According to Regulation (EC) No. 1907/2006

amended by Regulation (EU) No. 2020/878

Page 17 of 17

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

16.2	Abbreviations and acronym	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative			
16.3.	Key literature references an source of data:	d -			
16.4.	Classification and procedur 1272/2008 (CLP)	e used to derive the classification for mixture according to Regulation (EC)			
Classif	ication	Classification procedure			
-		-			
16.5.	Relevant H statements (nur	nber and full text)			
	H: 225	Highly flammable liquid and vapour.			
	314	Causes severe skin burns and eye damage.			
	335	May cause respiratory irritation.			
16.6.	Training advice:	-			
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to chemical safety assessment
-



Page 1 of 17

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

SECTI	ON 1: Identification of t	the substance	e/mixture	e and of the company/undertaking
1.1	Product identifier			
	Trading name:	TB FUCHSIN	N REAGEN	Т
	Chemical name:	-		
	Catalogue number:	TBFR-OT-X	**	
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against
	Uses:		For use	with TB-Stain ECO kit.
	Uses advised against:		Only the	e 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 p	erson:	msds@biognost.hr	
	National contact:		-	
1.4	Emergency telephone	number		
	National Protection an	d Rescue Dire	ectorate:	112
	Medical information:			+385 1 2348 342
	Other information:			-

SECTIO	SECTION 2. Hazards identification					
2.1	Classification of the substar	Classification of the substance or mixture				
2.1.1	Classification according to F	Regulation (EC) No 12	272/2008 (CLP)			
	Hazard class and ca	Hazard class and category code: Hazard statements*:				
	Flam. Liq. 3		H226			
2.1.2.	Additional information					
	-					
*For fu	Ill text of Hazard- and EU Haza	ard-statements: see S	SECTION 16			
2.2	Label elements					
	Product identification:	TB FUCHSIN RE	AGENT			
***************************************	Identification number:	-				
	Authorization number:	-				



Page 2 of 17

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

	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.			
	Supplemetal hazard information (EU):	-			
2.3	Other hazards				
	The product has no other know	n 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. Co	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			

SECT	SECTION 4. First aid measures						
4.1	Description of first aid measur	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.					



Page 3 of 17

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

	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	-	cal attention and special treatment needed ne body, obtain medical treatment (gastric lavage, activated carbon).	

SECTI	ON 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 su	ubstance 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 s water spray. Use water spray to dis	elf-contained breathing apparatus. Cool the fire affected containers with ssipate alcohol vapours.	
5.4	Additional information		
	-		



Page 4 of 17

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

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:			
	ventilation. Vapours may accu	and clothing and inhaling gases, vapours and aerosols. Ensure adequate mulate at floor level in low and confined spaces. Remove all heat, ignition chines. Ignition spark arrestor must not be operated in the danger area. Use 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 con-	tainment and cleaning up		
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.		
6.3.2.	Cleaning up:	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).		
	Reference to other sections			
6.4	Reference to other sections			

SECTIO	SECTION 7. Handling and storage		
7.1	Precautions for safe handling		
7.1.1.	Protection measures		



Page 5 of 17

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

	Measures to prevent fire:	Use in well ventilated storage rooms away from heat, hot surfaces, sparks flames and other ignition source smoking. Use non-sparkling tools equipment.	, open s. No	
	Measures to prevent aerosol and dust generatio	n: Ensure adequate ventilation.		
	Measures to protect the environment:	Prevent spilling into the sewage syste and waterways.	m	
	Other measures:	Protect against electrostatic charges.		
7.1.2.	Advice on general occupational hygiene:			
	Do not eat, drink or smoke in the workspace. The	proughly wash hands after work and before eating.		
7.2	Conditions for safe storage, including any incom	oatibilities		
	Technical measures and storage conditions:	Store in a well-ventilated place, protected from su away from sources of heat and ignition, in its of unopened and hermetically sealed packaging, from oxidizing agents, food, feed and artic consumption.	riginal, away	
	Packaging materials:	Manufacturer's original packaging. Keep away from food and drink. Keep the containers tightly closed.		
	Requirements for storage rooms and vessels:			
	Advices for storage equipment:	The storage must be made of hard material; floor be resistant to chemicals. There must be no draidirectly leads into sewage system. Secure ventilation.	in that	
	Further information on storage conditions:	Do not place the unused material in the storage and do not use empty containers for storing chemicals. Do not store with incompatible material Section 10).	other	
7.3	Specific end use(s)			
	Recommendations:	-		
	Industrial sector specific solutions:	-		

SECTION 8. Exposure controls/personal protection				
8.1 Control parameters				
Substance	CAS No		exposure limit term values	Biological limit values
		ppm	mg/m³	-
Ethanol	64-17-5	1000/-	1900/-	-
Substance name: -				



Structural measures to prevent

exposure:

SAFETY DATA SHEET According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

							Page 6 of 17
Trading nam	ne:			Т	B - FUC	HSIN REAGENT	
Product code	e: ⁻	TBFR-OT-X**		Revisio	on date:	23 Dec 2022	Version: 2
EC No:		- CAS	No:	-			
DNEL							
				Inc	dustrial		Γ
Route of		Acute		Acute .		Chronic	Chronic
exposure:		effect local	effe	ct systemic	C	effect local	effect systemic
Oral	-	1000 / 3	-		-		-
Inhalation		1900 mg/m³ (ethanol)	-		-		380 mg/m³ (ethanol)
Dermal	-		-		-		343 mg/kg (ethanol)
Critical physic	al parar	meters: solubili	ty, flamm	ability, cor	rosivity:	-	
		1		Co	nsumer		
Route of		Acute		Acute		Chronic	Chronic
exposure:		effect local	effe	effect systemic		effect local	effect systemic
Oral		-	-		-		87 mg/kg bw/day (ethanol)
Inhalation		950 mg/m ³ (ethanol)	-		-		114 mg/m³ (ethanol)
Dermal		-	-		-		206 mg/kg (ethanol)
PNEC							
Environmenta	l protec	ction target			PNEC		
Fresh water					0.96 mg/	/l (ethanol)	
Freshwater se	diments	S			3.6 mg/k	(g (ethanol)	
Marine water					0.79 mg/	(I (ethanol)	
Marine sedime	ents				2.9 mg/kg (ethanol)		
Food chain					380-720 mg/kg (ethanol)		
Microorganisr	ms in se	wage treatme	nt		580 mg/l (ethanol)		
Soil (agricultu	ral)				0.63 mg/kg (ethanol)		
Air				no information available			
8.2 E	xposure	sure controls					
8.2.1. A	Appropr	iate engineerir	ng control	s			
	Appropriate engineering controls Substance/mixture related measures to prevent exposure during identified uses:			concentro concentro existing	ration limit it is the ration levels down t	naterial with no controlled e employer's duty to keep o a minimum achievable by nological means, where the no harm to workers.	

In accordance with Section 7.



Page 7 of 17

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

	Organisational measures to prever exposure:	nt	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:		propriate, chemical-proof protective glasses/face shield (EN 321-1:2022, EN 166).	
8.2.2.2.	Skin protection			
	Hand protection: Use app		propriate, chemical-resistant protective gloves (EN 374).	
	Other skin protection:	Use ap	propriate protective clothing.	
8.2.2.3.	Respiratory protection:	concer in the contac	e of normal usage and ventilation, it is not necessary. If ntration of ethyl alcohol exceeds occupational exposure limits air, use a self-contained breathing apparatus. For short at and if the oxygen content of the air is greater than 18 %, use ective gas mask with filter A (EN 14837/A1).	
8.2.2.4.	Thermal hazards:	No the	ermal hazards known.	
8.2.3.	Environmental exposure controls			
	Substance/mixture related measures to prevent exposure:	See Se	ction 6	
	Structural measures to prevent exposure:	Use mo	odern equipment.	
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.	
	Technical measures to prevent exposure:	See Se	ection 6	

SECT	SECTION 9. Physical and chemical properties				
9.1	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		



Page 8 of 17

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

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

SECTIO	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 Inform	1.1 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				



Page 9 of 17

Trading name:		TB - FUCHSIN REAGENT								
Product code:	TBFR	-OT-X**	R	evision	date:	23 De	2022	Vers	ion:	2
	·		:							
Inhalation:		-	rat (ethanol)		LC ₅₀		4 h		>8.000 r	ng/l
Specific	target or	gan toxicit	y – single exp	osure (S	TOT SE):					
		Spec	ific effects			gan	Note			
Oral:	No ir	nformation	available		No info	ormation av	ailable	_		
Dermal:	No ir	No information available			No info	ormation av	ailable	_		
Inhalation:	No ir	nformation	available		No info	ormation av	ailable	-		
Aspiration	1	No infor	mation a	vailable.						
Irritation	and cor	rosion								
	·	Exposur	e time	Spec	ies	Evaluation	n Method		Note	
Skin	_		-			_	_	_		
corrosion/irritation	on:									
Serious eye damage/irritatior	_		-			-	-	_		
damage/imtation	I									
Sensitiza	ation									
Skin sensitization	:	No inf	ormation ava	ilable.						
Respiratory sensi	tization:	No inf	ormation ava	ilable.						
		,								
Symptoi	ms relate	d to the ph	nysical, chemi	cal and t	oxicolog	ical charact	eristics			
·	Ak	sorption	of great	quantitie	es may	cause c	lizziness, dru	nkenness,	euph	oria,
Oral exposure:				•	_		llowing great	•		and
			-			·	e may lead to			
Dermal exposure	•	ter prolon acking of s	•	ated exp	oosure s	symptoms	may include:	defatting,	drynes	s and
Inhalation exposu	ıra.	halation of embranes.	great quantit	ies may (cause diz	ziness, eup	horia and mild	irritation	of the m	ucous
Eye exposure:	М	ay cause ir	ritation and re	edness.						
Repeate	d dose to	oxicity (sub	acute, subchr	onic, ch	ronic)					
, .	D	ose	Exposure time	Speci	es	Method	Evaluat	ion	Note	
Subacute oral No infavailable		ormation e	No information available	No inforr availa	nation ble	No informati available	on No info	ormation le	_	



Page 10 of 17

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

Subacute dermal	No infor available	mation	No information available	No information available	No information available	No inform available	nation	-
Subacute inhalation	No infor available	mation	No information available	No information available	No information available	No inform available	nation	-
Subchronic oral	No infor available	mation	No information available	No information available	No information available	No inform available	nation	-
Subchronic dermal	No infor available	mation	No information available	No information available	No information available	No inform available	nation	-
Subchronic inhalation	No information available		No information available	No information available	No information available	No inform available	nation	-
Chronic oral	No information available		No information available	No information available	No information available	No inform available	No information available	
Chronic dermal	No infor available	mation	No information available	No information available	No information available	No information available		-
Chronic inhalation	No infor available	mation	No information available	No information available	No information available	No inform available	nation	-
				vnosura (STOT	BE).			
Specific	target orga	n tovicit	V — ranaataa a					
Specific	target orga	n toxicit	· ·	•		rgan		Note
: -			y – repeated e Specific effec ation available	•	Target o		_	Note
: -	No	informa	Specific effec	•	Target o	n available	-	Note
Subacute oral Subacute derma	No I No	informa informa	Specific effection available	•	Target o	n available n available		Note
Subacute oral Subacute derma Subacute inhalat	No I No tion No	informa informa informa	Specific effection available ation available	•	Target o No information	n available n available n available	-	Note
Subacute oral Subacute derma Subacute inhalat Subchronic oral	No I No tion No	informa informa informa informa	Specific effect ation available ation available ation available	•	Target o No information No information No information	n available n available n available n available	-	Note
Subacute oral Subacute derma Subacute inhalat Subchronic oral Subchronic derm	No I No tion No No	informa informa informa informa informa	Specific effect ation available ation available ation available ation available	•	Target o No information No information No information No information	n available n available n available n available n available	-	Note
Subacute oral Subacute derma Subacute inhalat Subchronic oral Subchronic dern Subchronic inhal	No I No tion No No nal No lation No	informa informa informa informa informa	Specific effect ation available ation available ation available ation available	•	Target o No information No information No information No information No information	n available n available n available n available n available n available	-	Note
Subacute oral	No I No tion No nal No lation No	informa informa informa informa informa informa informa	Specific effect ation available ation available ation available ation available ation available	•	Target o No information No information No information No information No information No information	n available n available n available n available n available n available n available	-	Note



Page 11 of 17

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

	Mutagenicity in vitro:	Based on available data, the classification criteria are not met.				
	Genotoxicity:	Based on available data, the classification criteria are not met.				
	Mutagenicity in vivo:	Based on available data, the classification criteria are not met.				
	Germ cell mutagenicity:	Ba	sed on available data, the classification criteria are not met.			
	Reproductive toxicity: Based on available data, the classification criter					
	Summary of evaluation of the CN properties:	ЛR	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. Ecologic	cal informat	ion				
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	-



Trading name:

SAFETY DATA SHEET According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

TB - FUCHSIN REAGENT

Page 12 of 17

Product code:	Т	BFR-OT-X*	*	Re	evision date:	23 Dec 2	2022	Version:		2
Algae/aquatic p	lants	IC ₅₀	72 hours	•	No information available	No information available		No information available		
Other organism	S	-	-	-		-	-		-	
12.2 Persist	ence a	nd degrada	bility							
Abiotic	degra	adation				:		-		
	De	egradation h	alf-lives		Method	Evaluat	tion		Note	
Marine water	No ii	lo intormation available			information lable	No informat available	ion	-		
Fresh water	No ii	In information available			information lable	No informat available	rion	–		
Air	No ir	o intormation available			information lable	No informat available	ion	-		
Soil	No information available			information lable	No information available		-			
Biodeg	ıradati	on								
% Degradation	n	Time (days)		Method	Evaluat	tion		Note	
No information			formation		information	No informat	ion	No inform	ation	
available		available		ava	ilable	available		available		
12.3 Bioacci	و الموريا م	tivo notontis	1							
		tive potentia		log K	ow)					
Value		er partition of centration	pH	°C	Method	Eve	aluation		Note	
value	-	Centration	-	-	-	_ Lvc	aluation	_	Note	
_			_							
Biocon	centra	tion factor (BCF)							
Value		Speci		0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Method	Evalu	ation		Note	
	N	· · · · · · · · · · · · · · · · · · ·	formation	No i	information	No inform				
-		vailable			lable	available		-		
			<u> </u>							



Page 13 of 17

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

	Chronic	ecoto	xicity				:				:
	Value		Dose	Exposure time	9	Species	Meth	od	Ev	aluation	Note
Chronic	toxicity (on fish	LC ₅₀	No information available		ormation ailable	No informa availab			rmation lable	-
Chronic toxicity on crustacea (<i>Daphnia</i>)			No information available		ormation ailable	No informa availab		1	rmation lable	-	
12.4	Mobility	y in soi	I								
	Known	or pred	dicted distributi	on in enviror	menta	ıl compart	ments:				
	No info	rmatio	n available								
	Surface	tensio	n:								
	Valu	ıe	°C	Concen	tration		Metho	d			Note
	No informa availabl		No information available	No information available			No information - available		-		
	Adsorp	tion / c	desorption								
Transpo		A/[D coefficient ory's constant	log Kov	,	Evaporation rate			Method		Note
Soil-wa	ter	No availa	information able	No informa available		No inform available	nation	No ii avail	nform able	ation	-
Water-	air	No availa		No informa available		No inform available		avail			-
Soil-air		No availa	information able	No informa available		No inform available	nation	No in	nform able	ation	-
12.5			and vPvB asses								
	Based c	n avai	lable data, the p	product does	not co	ntain any	PBT or v	PvB su	ıbstar	ices.	



Page 14 of 17

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

12.7.	Other adverse effects	2.7. Other adverse effects						
	Do not let the product or its res	idues reach sewer system, waterways and soil.						
SECTION	13. Disposal considerations							
13.1	Waste treatment methods							
13.1.1.	Product/Packaging disposal:							
	Submit for disposal to the leg Protection.	al person authorized by the Ministry of Environmental and Nature						
13.1.2.	Waste codes/waste designation	ons 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.	.4. Sewage disposal – relevant information:							
	Waste must not be disposed of	of into the sewage system.						
13.1.5.	Other disposal recommendati							
	authorized by the ministry in	ct's remains into the sewage system. Submit the remains to the collectors charge. Do not dispose of the packaging into the sewage system. Submit ors authorized by the ministry in charge. Unused product residues may be						
13.1.6.	Relevant Community provisio	ns:						
	Disposal must be made accor	ding to official regulations.						
SECTION	14 TRANSPORT INFORMATION	ON						
-	Transporting/shipment by road	(ADR)						
UN numb	per:	1170						
UN prope	er shipping name:	Ethanol solution						
•	t hazard class(es):	3						
Packing g		III						
	entally hazardous:	-						
	recautions for user:	-						
	Transporting/shipment by rail (I							
UN numb	N number: 1170							



SAFETY DATA SHEET According to Regulation (EC) No. 1907/2006

amended by Regulation (EU) No. 2020/878

Page 15 of 17

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

UN proper shipping name:		Ethanol solution		
Transport hazard class(es	5):	3		
Packing group:		III		
Environmentally hazardous:		-		
Special precautions for u	ser:	-		
Inland waterway	transport (ADN)			
UN number:		1170		
UN proper shipping nam	ie:	Ethanol solution		
Transport hazard class(es	5):	3		
Packing group:		III		
Environmentally hazardo	us:	-		
Special precautions for u	ser:	-		
Transporting/sh	ipment by sea (IN	MDG)		
UN number:		1170		
UN proper shipping name:		Ethanol solution		
Transport hazard class(es	5):	3		
Packing group:		III		
Environmentally hazardo	us:	-		
Special precautions for u	ser:	-		
Transport in bulk accord of MARPOL 73/78 and the		-		
Transporting/sh	ipment by air (IC	AO-TI/IATA-DGR)		
UN number:		1170		
UN proper shipping nam	ie:	Ethanol solution		
Transport hazard class(es	5):	3		
Packing group:		III		
Environmentally hazardous:		-		
Special precautions for user:		-		
ADR: Special provision 144 - Aqueous solution containing 24% or less alcohol volume not subjected to classification. IATA: Special provision A58 - Aqueous solution containing 24% or less alcohol volume not subjected to classification.				

SECTION 15. Regulatory information

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



Page 16 of 17

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

	EU regulations	
	Authorization and/or rest	rictions of use
	Authorizations:	-
	Restrictions:	-
		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; 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;
	Other EU regulations:	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; 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; 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).
		REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	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 assessme	ent
	None	

SECTION 16. Other information		
16.1 Indication of changes:	-	



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

Page 17 of 17

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

16.2	Abbreviations and acronym	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative	
16.3.	Key literature references an source of data:	d _	
16.4.	Classification and procedur 1272/2008 (CLP)	e used to derive the classification for mixture according to Regulation (EC)	
Classifi	cation	Classification procedure	
_		-	
16.5.	Relevant H statements (nur	nber and full text)	
	H: 225	Highly flammable liquid and vapor.	
	226	Flammable liquid and vapor.	
16.6.	Training advice:	-	
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.	

ANNEX: Exposure scenario resulting to chemical safety assessment	
-	



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

Page 1 of 17

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

SECT	ION 1: Identification of	the substanc	e/mixture	e and of the company/undertaking		
1.1	Product identifier					
	Trading name:	METHYLEN	METHYLENE BLUE LOEFFLER'S REAGENT			
	Chemical name:	-	-			
	Catalogue number:	MBL-OT-X	**			
1.2	Relevant identified us	es of the subs	stance or n	nixture and uses advised against		
	Uses:		For stair	ning in microbiology and histology.		
	Uses advised against:		Only the	e identified uses are advised. Unsuitable for human nption.		
	Reason why uses advi	sed against:	device,	duct is intended for use only as an <i>in vitro</i> diagnostic medical registered at the Agency for Medicinal Products and Medical 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 p	person:	msds@l	<u>biognost.hr</u>		
	National contact:		-			
1.4	Emergency telephone	Emergency telephone number				
	National Protection a	nd Rescue Dir	ectorate:	112		
	Medical information:	al information:		+385 1 2348 342		
	Other information:			-		

SECTIO	SECTION 2. Hazards identification			
2.1	Classification of the substance or mixture			
2.1.1	Classification according to Regu	ulation (EC) No 12	72/2008 (CLP)	
	Hazard class and catego	ory code:	Hazard statements*:	
	Flam. Liq. 3		H226	
2.1.2.	Additional information			
	-			
*For ful	ll text of Hazard- and EU Hazard-	statements: see S	ECTION 16	
2.2	Label elements			
	Product identification:	METHYLENE BLU	JE LOEFFLER'S REAGENT	
	Identification number:	-		
	Authorization number:	-		



Page 2 of 17

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

	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.
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	The product has no other kno	wn specific hazards for human or environment.
	Results of PBT and vPvB asses PBT or vPvB substances.	sment: Based on available data, the product does not contain any
	Endocrine disrupting property	y: Based on available data, does not contain endocrine disruptors.

SECTION 3. Co	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			

SECT	SECTION 4. First aid measures				
4.1	Description of first aid measu	res			
	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.			



Page 3 of 17

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

	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 ef	fects, 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).		

SECTI	ON 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 s water spray. Use water spray to dis	elf-contained breathing apparatus. Cool the fire affected containers with ssipate alcohol vapours.
5.4	Additional information	
	-	



Page 4 of 17

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

SECTIO	ON 6. Accidental release measu			
6.1	Personal precautions, protective	e 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:			
	ventilation. Vapours may accur	and clothing and inhaling gases, vapours and aerosols. Ensure adequate mulate at floor level in low and confined spaces. Remove all heat, ignition chines. Ignition spark arrestor must not be operated in the danger area. Use 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.			
	· ·	e resulting waste to enter sewers/soil/surface or ground water. Notify the		
6.3	· ·	e resulting waste to enter sewers/soil/surface or ground water. Notify the dance with local law in the case of environmental pollution immediately.		
6.3 6.3.1.	respective authorities in accord	e resulting waste to enter sewers/soil/surface or ground water. Notify the dance with local law in the case of environmental pollution immediately.		
	respective authorities in accord Methods and material for cont Bunding, covering of drains;	e resulting waste to enter sewers/soil/surface or ground water. Notify the dance with local law in the case of environmental pollution immediately.		
6.3.1.	methods and material for cont Bunding, covering of drains; capping procedures:	e resulting waste to enter sewers/soil/surface or ground water. Notify the dance with local law in the case of environmental pollution immediately. Sainment and cleaning up Sand protective barrier or barriers made of similar materials. 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		
6.3.1.	methods and material for cont Bunding, covering of drains; capping procedures: Cleaning up:	e resulting waste to enter sewers/soil/surface or ground water. Notify the dance with local law in the case of environmental pollution immediately. Sand protective barrier or barriers made of similar materials. 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). Secure proper ventilation. Do not use incompatible materials (see Section		

SECTIO	SECTION 7. Handling and storage		
7.1	Precautions for safe handling		
7.1.1.	Protection measures		



Page 5 of 17

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

	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 generatio	n:	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. The	oroughly was	sh hands after work and before eating.	
7.2	Conditions for safe storage, including any incom	patibilities		
	Technical measures and storage conditions:	away from unopened	well-ventilated place, protected from sunlight, a sources of heat and ignition, in its original, and hermetically sealed packaging, away dizing agents, food, feed and articles of ion.	
	Packaging materials:	Manufactu	ufacturer's original packaging. away from food and drink. Keep the containers ly closed.	
	Requirements for storage rooms and vessels:	Keep away tightly clos		
	Advices for storage equipment:	be resistar	ge must be made of hard material; floors must nt to chemicals. There must be no drain that eads into sewage system. Secure proper n.	
	Further information on storage conditions:	Do not place the unused material in the storage and do not use empty containers for storing chemicals. Do not store with incompatible materials Section 10).		
7.3	Specific end use(s)			
	Recommendations:	-		
	Industrial sector specific solutions:	-		

SECTION 8. Exposure controls/personal protection										
8.1 Control parameters	Control parameters									
Substance	CAS No		exposure limit term values	Biological limit values						
		ppm	mg/m³	_						
Ethanol	64-17-5	1000/-	1900/-	-						
		•								
Substance name: -										



Page 6 of 17

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

		,								
EC No:		-	CAS No	:	-					
DNEL										
	Industrial									
Route of		Acu	ıte		Acute		Chron	nic	Chronic	
exposure:		effect	local	effe	ect systemi	С	effect lo	ocal	effect systemic	
Oral		-		-		-			-	
Inhalation		1900 mg (ethanol)		-		-			380 mg/m³ (ethanol)	
Dermal		-		-		-			343 mg/kg (ethanol)	
Critical phy	sical par	ameters: s	olubility,	flamm	nability, co	rrosivity	<i>/</i> : -			
					Co	nsume	r			
Route of		Ad	cute		Acute		Chron	nic	Chronic	
exposure:		effec	t local	effe	ect systemi	ic	effect lo	ocal	effect systemic	
Oral		-		-		-			87 mg/kg bw/day (ethanol)	
Inhalation		950 m (ethan	-	-		-			114 mg/m³ (ethanol)	
Dermal		-		-		-			206 mg/kg (ethanol)	
PNEC						_				
Environmer	ntal prot	ection tar	get			PNEC				
Fresh water						0.96 mg/l (ethanol)				
Freshwater	sedimer	nts				3.6 mg/kg (ethanol)				
Marine wat	er					0.79 mg/l (ethanol)				
Marine sed	iments					2.9 mg/kg (ethanol)				
Food chain						380-720 mg/kg (ethanol)				
Microorgan	isms in	sewage tr	eatment			580 mg/l (ethanol)				
Soil (agricu	ltural)					0.63 mg/kg (ethanol)				
Air						no inf	ormation av	ailable		
8.2	Exposu	ire contro	ls							
8.2.1.	Appropriate engineering controls									
	Substance/mixture related measures to prevent exposure during identified uses:			conce conce existir	ntration lim ntration lev ng scientific	nit it is the vels down to and techr	naterial with no controlled e employer's duty to keep o a minimum achievable by nological means, where the no harm to workers.			
	Structu exposu	ıral measu ıre:	ires to pr	event		In accordance with Section 7.				



Page 7 of 17

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

	Organisational measures to preve exposure:	nt	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent exp	oosure:	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:		propriate, chemical-proof protective glasses/face shield (EN 321-1:2022, EN 166).			
8.2.2.2.	Skin protection					
	Hand protection:	Use ap	e appropriate, chemical-resistant protective gloves (EN 374).			
	Other skin protection:	Use ap	appropriate protective clothing.			
8.2.2.3.	Respiratory protection:	concer in the contac	e of normal usage and ventilation, it is not necessary. If ntration of ethyl alcohol exceeds occupational exposure limits air, use a self-contained breathing apparatus. For short at and if the oxygen content of the air is greater than 18 %, use ective gas mask with filter A (EN 14837/A1).			
8.2.2.4.	Thermal hazards:	No the	ermal hazards known.			
8.2.3.	Environmental exposure controls					
	Substance/mixture related measures to prevent exposure:	See Se	ction 6			
	Structural measures to prevent exposure:	Use mo	odern equipment.			
	Organisational measures to prevent exposure:	Adapt workpl	pt the work process to the required working conditions of the kplace.			
	Technical measures to prevent exposure:	See Se	ction 6			

SECTI	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							



Page 8 of 17

Trading name:	ı				
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

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

SECTIO	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.					

SECTIO	SECTION 11. Toxicological information											
11.1	Information	Information on hazard classes as defined in Regulation (EC) No 1272/2008										
	Acute toxic	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						



According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

Page 9 of 17

Trading name:	METHYLENE BLUE LOEFFLER'S REAGENT								
Product code:	V	1BL-OT-X**	Revision		date:	23 De	ec 2022	Versi	on: 9
Inhalation:		-	rat (ethanol)		LC ₅₀)	4 h	2	>8.000 mg/l
Specific	c targe	t organ toxicit	v – single exp	osure (S	TOT SE)				
<u> </u>			ific effects			Target or	gan	1	Note
Oral:	N	lo information			No info	ormation av		-	
Dermal:	٨	lo information	available		No info	ormation av	vailable	-	
Inhalation:	٨	lo information	available		No info	ormation av	vailable	-	
Aspirat	ion ha	zard:	N	No infor	mation a	vailable.			
Irritatio	n and	corrosion							
		Exposur	e time	Spec	ies	Evaluatio	n Method		Note
Skin corrosion/irritat	ion:	-	-			-	-	-	
Serious eye damage/irritatio	n	-	_			-	_	-	
C : + : -	4:								
Skin sensitizatio		No inf	ormation avai	lablo					
Respiratory sens			ormation avai						
Trespiratory series	J.C.Z.G.C.	J.I. 110 III	omation avai	14510.					
Sympto	oms re	lated to the pl	nysical, chemic	cal and t	oxicolog	jical charac	teristics		
Oral exposure:				nol poiso	oning. In	case of swa	dizziness, dru allowing great e may lead to	•	nausea and
Dermal exposur	e:	After prolon cracking of s		ated exp	oosure s	symptoms	may include:	defatting,	dryness and
Inhalation expos	sure:	Inhalation of membranes.	great quantiti	es may o	cause diz	zziness, eup	phoria and milo	l irritation o	of the mucous
Eye exposure:		May cause ir	ritation and re	edness.					
1									
Repeat	ed dos	se toxicity (sub	acute, subchr	onic, chi	ronic)				
		Dose	Exposure time	Speci	es	Method	Evalua	tion	Note
Subacute oral	No avai	information lable	No information available	No inforr availa	nation ble	No informat available	ion availah	ormation ole	-



Page 10 of 17

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

Subacute dermal	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Subacute inhalation	No availa	information able	No information available	No information available	No information available	No inform	nation	
Subchronic oral	No availa	information able	No information available	No information available	No information available	No inform available	nation	–
Subchronic dermal	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Subchronic inhalation	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Chronic oral	No availa	information able	No information available	No information available	No information available	No inform available	nation	_
Chronic dermal	No availa	information able	No information available	No information available	No information available	No inform	nation	-
Chronic	No availa	information able	No information available	No information available	No information available	No inform	nation	-
inhalation			available		G. T. G. T. G. T. G.			
<u> </u>	target	organ toxicit		xposure (STOT				
<u> </u>	target	organ toxicit	y – repeated e	xposure (STOT	RE):	rgan		Note
Specific	target			•			_	Note
<u> </u>		No informa	y – repeated e Specific effec	•	RE): Target o	n available	-	Note
Specific Subacute oral Subacute derma	l	No informa	y – repeated e Specific effec ation available	•	RE): Target o	n available n available		Note
Specific Subacute oral	l	No informa No informa No informa	y – repeated e Specific effec ition available ition available	•	RE): Target o No information	n available n available n available		Note
Specific Subacute oral Subacute derma Subacute inhala	l	No informa No informa No informa No informa	y – repeated e Specific effec ation available ation available	•	RE): Target of the No information of the No	n available n available n available n available	-	Note
Specific Subacute oral Subacute derma Subacute inhalat Subchronic oral Subchronic dern	l :ion nal	No informa No informa No informa No informa No informa	y – repeated e Specific effect ation available ation available ation available	•	RE): Target of the No information No information No information No information No information	n available n available n available n available n available	-	Note
Specific Subacute oral Subacute derma Subacute inhalat Subchronic oral Subchronic dern Subchronic inha	l :ion nal	No informa No informa No informa No informa No informa No informa	y – repeated e Specific effect ation available ation available ation available ation available	•	RE): Target of No information	n available n available n available n available n available n available	-	Note
Specific Subacute oral Subacute derma Subacute inhalat Subchronic oral	l :ion nal	No informa	y – repeated e Specific effect ation available ation available ation available ation available ation available	•	RE): Target of No information	n available n available n available n available n available n available	-	Note



Page 11 of 17

Trading name:	М	ETHYLENE BLUE LO	EFFLER'S REAGENT		
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

	Mutagenicity in vitro:	Bas	sed on available data, the classification criteria are not met.	
	Genotoxicity:	Bas	sed on available data, the classification criteria are not met.	
	Mutagenicity in vivo:	Bas	sed on available data, the classification criteria are not met.	
	Germ cell mutagenicity:	Bas	sed on available data, the classification criteria are not met.	
	Reproductive toxicity:	Bas	sed on available data, the classification criteria are not met.	
	Summary of evaluation of the CN 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. Ecologic	cal informat	ion				
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	_



Page 12 of 17

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

Algae/aquatic	plants	IC ₅₀	72 hours		No information available	No informati available	on i	o information vailable	-
Other organisr	ns	-	-	-	-	-	-		-
		nd degrada	bility						
Abiot		adation	16.11	**************************************					
	De	egradation h	nalt-lives		Method		uation		Note
Marine water	No i	nformation	available		information ilable	No inforr available	nation	-	
Fresh water	No i	nformation	available		information ilable	No inforr available	nation	-	
Air	No i	nformation	available		information ilable	No inforr available	mation	-	
Soil	No i	nformation	available		information ilable	No inforr	mation	-	
% Degradat No information available		Time (No ii available	days)		Method information ilable	Eval No inforr available	uation nation	No inform available	Note nation
		tive potenti							
Value		er partition of the contraction	pH	°C	Method		Evaluatio	nn .	Note
Log Pow: ~ 0.32	-	icentiation	•	-	-	-	Lvaluatio	The pro	oduct does no umulate
Bioco	ncentra	ation factor	(BCF)						
Value		Spec	es		Method	Eva	aluation		Note
BCF: 0.66		lo ir vailable	formation		information lable	No info availabl	rmation e	-	



According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

Page 13 of 17

Trading name:	M	ETHYLENE BLUE LO	EFFLER'S REAGENT		
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

	Chronic	ecoto	xicity							
	Value		Dose	Exposure time	Specie	es	Method	Ev	aluation	Note
Chroni	ronic toxicity on fish LC ₅₀		LC ₅₀	No information available	No informa available		o Iformation vailable	_	rmation lable	-
	c toxicity cea (<i>Daph</i>		EC ₅₀	No information available	No informa available		o Iformation vailable		rmation lable	-
12.4	Mobilit	v in soi	I							
		-		on in environme	ental con	npartme	nts:			
		···········	n available			F =				
	Surface									
	Valu		°C	Concentrat	ion	N	Лethod			Note
	No informa availab		No information available	No informati available	No information No information		-			
	Adsorp	tion / c	desorption							
Transp		A/[D coefficient ry's constant	log Kow	Evap	oration	rate	Meth	od	Note
Soil-wa	ater	No availa	information able	No informatio	n No ir availa	nformati able		nform lable	ation	-
Water-	air	No availa	information able	No information available	n No information available		on No information available		ation	-
Soil-air	•	No availa	information able	No information available	n No ir availa	nformati able		nform lable	ation	-
12.5	Results	of PBT	and vPvB asses	ssment						
	Based o	on avail	able data, the p	product does no	t contain	any PB	T or vPvB s	ubstar	ices.	
-										



Page 14 of 17

Trading name:	N	IETHYLENE BLUE LO	EFFLER'S REAGENT		
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

12.7.	Other adverse effects	
	Do not let the product or it	s residues reach sewer system, waterways and soil.
SECTIO	N 13. Disposal consideration	ons
13.1	Waste treatment method	s
	:	
13.1.1.	Product/Packaging dispo	sal:
	Submit for disposal to the Protection.	e legal person authorized by the Ministry of Environmental and Nature
13.1.2.	Waste codes/waste desig	nations according to Law:
	Packaging that contains r	residual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste treatment – releva	nt information:
	No information available	
13.1.4.	Sewage disposal – releva	nt information:
	Waste must not be dispo	sed of into the sewage system.
13.1.5.	Other disposal recommer	
	authorized by the ministr	oduct's remains into the sewage system. Submit the remains to the collectors by in charge. Do not dispose of the packaging into the sewage system. Submit lectors authorized by the ministry in charge. Unused product residues may be
13.1.6.	Relevant Community pro	visions:
	Disposal must be made a	ccording to official regulations.
SECTIO	N 14 TRANSPORT INFORM	IATION
	Transporting/shipment by i	road (ADR)
UN nun	nber:	1170
UN pro	per shipping name:	Ethanol solution
Transpo	ort hazard class(es):	3
Packing	group:	III
Environ	mentally hazardous:	-
Special	precautions for user:	-
	Transporting/shipment by I	rail (RID)
UN nun	nber:	1170



According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

Page 15 of 17

Trading name:		METHYLENE BLUE I	OEFFLER'S REAGEN	Т	
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway trans	port (ADN)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	lii e
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipme	t by sea (IMDG)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	lii e
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to of MARPOL 73/78 and the IBC	: -
Transporting/shipme	t 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: vol	E: Special Provision 144 – An aqueous solution containing 24% or less alcohol by me is not subject to classification. A: Special Provision A58 - An aqueous solution containing 24% or less alcohol by me is not subject to classification.

SECTION 15. Regulatory information

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



Page 16 of 17

Trading name:	М	ETHYLENE BLUE LO	EFFLER'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:	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; 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; 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; 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; 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).	
		dangerous substances, mixtures and articles (Annex XVII);	
	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 assessme	ent	
	None		

SECTION 16. Other information	
16.1 Indication of changes:	-



According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

Page 17 of 17

Trading name:	М	ETHYLENE BLUE LO	EFFLER'S REAGENT		
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

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

1	ANNEX: Exposure scenario resulting to chemical safety assessment
-	-