

TB-STAIN HOT KIT

The kit contains:

TB Carbol Fuchsin reagent TB Decolorizer Methylene Blue Loeffler reagent



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Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

	CTION 1: Identification of the substance/mixture and of the company/undertaking				
1.1	Product identifier				
	Trading name:	TB CARBOL	FUCHSIN	REAGENT	
	Chemical name:	-			
	Catalogue number:	TBC-OT-X**	k		
1.2	Relevant identified use	es of the subs	tance or m	nixture and uses advised against	
	Uses:		For use i	n TB-Stain Cold, TB-Stain Hot kit and TB-Stain Quick kits.	
	Uses advised against:		Only the	identified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplier of the safety data sheet				
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent 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 substance or mixture				
2.1.1	Classification according to Regulation (EC) No	o 1272/2008 (CLP)			
	Hazard class and category code:	Hazard statements*:			
	Flam. Liq. 3	H226			
	Muta. 2	H341			
	Acute Tox. 3	H331			
	Acute Tox. 3	H311			
	Acute Tox. 3	H301			
	Skin. Corr. 1B	H314			
	STOT RE 2	H373			
2.1.2.	Additional information				
	-				
*For fu	Ill text of Hazard- and EU Hazard-statements: se	ee SECTION 16			



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2.2	Label elements	
	Product identification:	TB CARBOL FUCHSIN REAGENT
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	GHS02 GHS05
	Signal word:	GHS06 GHS08 Danger
		H226 Flammable liquid and vapor.
	Hazard statements:	 H314 Causes severe skin burns and eye damage. H301 Toxic if swallowed. H311 Toxic in contact with skin. H331 Toxic if inhaled. H341 Suspected of causing genetic defects. H373 May cause damage to organs through prolonged or repeated exposure.
	Precautionary statements:	 P210 Keep away from heat/sparks/open flames/hot surfaces Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.
	Supplemetal hazard information (EU):	-
2.3	Other hazards	



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Endocrine Disrupting Properties:

No known endocrine disrupting properties

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

SECTION 3. 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	
107-21-1/ 203-473-3/ 603-027-00-1	-	10 - 20 %	ethylene glycol	Acute Tox. 4; H302	
108-95-2/ 203-632-7/ 604-001-00-2	01-2119471329- 32-xxxx	4 -5 %	phenol	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Skin Corr. 1B; H314 Muta. 2; H341 STOT SE 2; H373	

SECTI	SECTION 4. First aid measures				
4.1	Description of first aid measures				
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.			
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well- ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.			
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.			
	Following ingestion:	Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.			
	Self-protection of the first aider:	-			
4.2	Most important symptoms and effects, both acute and delayed				



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	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
1.3	Indication of any immediate	medical attention and special treatment needed
	-	

SECTI	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Water, foam, dry powder, CO ₂			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the substance or mixture				
	Hazardous combustion products:	Mixture with combustible ingredients. Forms explosive mixtures with air at elevated temperatures. Development of hazardous combustion gases or vapours possible in the event of fire. Vapours are heavier than air and may spread along floors.			
5.3	Advice for firefighters				
	Use a self-contained open-circuit	compressed air breathing apparatus and fireproof clothing.			
5.4	Additional information	Additional information			
	Cool endangered receptacles with contaminate the environment with	water spray. Collect contaminated fire fighting water separately. Do not nextinguishing media.			

SECTIO	SECTION 6. Accidental release measures					
6.1	Personal precautions, protective	equipment and emergency procedures				
6.1.1.	1. For non-emergency personnel					
	Protective equipment:	Use personal protective equipment (see Section 8).				
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.				
	Emergency procedures:	Mark the area using proper signs.				
6.1.2.	For emergency responders:					
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).					
6.2	Environmental precautions:					



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	Do not let product enter drains. Risk of explosion.				
6.3	Methods and material for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:				
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.			
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).			
6.4	Reference to other sections				
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.				

SECTIO	ON 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:		Use in well ventilated storage rooms. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge. Do not smoke.		
	Measures to prevent aerosol and dust generation	es to prevent aerosol and dust generation:			
	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	proughly was	sh hands after work and before eating.		
7.2	Conditions for safe storage, including any incom	patibilities			
	Technical measures and storage conditions:	well ventila	htly closed and upright set containers in a ated storage rooms at temperatures ranging 25 °C. Protect from heat and direct sunlight.		
	Packaging materials:	Manufactu	ırer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away tightly clos	r from food and drink. Keep the containers sed.		



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	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Expos	ure contro	ols/perso	onal protec	tion				
8.1 Control pa	arameters							
Substance		CA	S No			posure limit erm values		Biological limit values
				рр	m	mg/m³		-
Ethanol		64	-17-5	100	0/-	1900/-		-
Ethylene glycol	Ethylene glycol		7-21-1	20/	40	52/104		
Phenol		108	8-95-2	2/	4	8/16	mol	mg/g of creatinine (0.14 /mol of creatinine), end of t, urinary excretion
Substance name:	-		**					
EC No:	-	CAS No): –					
DNEL								
				Indu	strial			
Route of exposure:	Acu effect		Acut effect sys		е	Chronic ffect local		Chronic effect systemic
Oral	-		-		-			-
Inhalation	1900 mg (ethanol)		-		35 mg/k (ethylen	g e glycol)		380 mg/m ³ (ethanol) 8 mg/m ³ (phenol)
Dermal	-		-		-			343 mg/kg (ethanol) 106 mg/kg (ethylene glycol) 1.23 mg/kg (phenol)
Critical physical par	rameters: s	olubility,	flammabilit	ty, corros	sivity:	-		
				Cons	umer			



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Route of	Acute	Acute	Chronic	Chronic	
exposure:	effect local	effect systemic	effect local	effect systemic	
Oral	-	-	-	87 mg/kg (ethanol) 0.5 mg/kg (phenol)	
Inhalation	950 mg/ m ³ (ethanol)	-	7 mg/kg (ethylene glycol)	114 mg/m ³ (ethanol) 0.452 mg/m ³ (phenol)	
Dermal	-	-	-	206 mg/kg (ethanol) 0.5 mg/kg (phenol) 53 mg/kg (ethylene glycol)	
PNEC					
Environmental prote	ection target		PNEC		
Fresh water			0.96 mg/l (ethanol) 10 mg/l (ethylene glycol) 0.0077 mg/l (phenol)		
Freshwater sediments			3.6 mg/kg (ethanol) 37 mg/kg (ethylene glycol) 0.09125 mg/kg (phenol)		
Marine water			0.79 mg/l (ethanol) 1 mg/l (ethylene glycol) 0.00077 mg/l (phenol)		
Marine sediments			2.9 mg/kg (ethanol) 3.7 mg/kg (ethylene glycol) 0.00915 mg/kg (phenol)		
Food chain			380-720 mg/kg (ethanol)		
Microorganisms in sewage treatment			580 mg/l (ethanol) 199.5 mg/l (ethylene glycol) 2.1 mg/l (phenol)		
Soil (agricultural)			0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene glycol) 0.136 mg/kg (phenol)		
Air			no information available		

8.2	Exposure controls			
8.2.1.	Appropriate engineering controls			
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.		



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	Structural measures to prevent exposure:		In accordance with Section 7.	
	Organisational measures to prevent exposure:		Organization of work in order to reduce other worker's influence during work process.	
	Technical measures to prevent ex	(posure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.	
8.2.2.	Personal protection equipment			
8.2.2.1.	Eye and face protection:	levels o	glasses that stick to face (EN 166) or visor in case of lower of concentration in air; protective gas mask that covers the face in case of higher levels of concentration in air.	
8.2.2.2.	Skin protection			
	Hand protection:	Regula Full co Splash	Glove material: butyl rubber Glove thickness: 0.70 mm Break through time: > 480 min contact: Gloves material: nitrile rubber Glove thickness: 0.40 mm Break through time: > 120 min	
	Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover t entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemic (Viton, PVC, himex) and footwear made from the same material.		
8.2.2.3.	Respiratory protection:	with a	tive full face mask (EN 136) or half mask (EN 140) equipped filter for organic vapors, type "A" (boiling point >65°C) ing to EN 14387) used when concentration levels exceed	
8.2.2.4.	Thermal hazards:	No info	ormation available	
8.2.3.	Environmental exposure controls			
	Substance/mixture related measures to prevent exposure:	See Se	ction 6	
	Structural measures to prevent exposure:	Use m	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	ction 6	



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Information on basic physical and chemical properties						
	Value	Method				
Physical state:	liquid	No information available				
Colour:	dark pink	No information available				
Odour/odour threshold:	phenol 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				
Lover and upper explosion limit:	No information available	No information available				
Flash point:	48°C	No information available				
Auto-ignition temperature:	No information available	No information available				
Decomposition temperature:	No information available	No information available				
pH:	No information available	No information available				
Kinematic viscosity:	No information available	No information available				
Solubility:	No information available	No information available				
Partition coefficient n- octanol/water (log value):	No information available	No information available				
Vapour pressure:	No information available	No information available				
Density and/or relative density:	No information available	No information available				
Relative vapour density:	No information available	No information available				
Particle characteristics:	No information available	No information available				

SECTIO	SECTION 10. Stability and reactivity					
10.1	Reactivity: See subsections 10.3 through 10.5.					
10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).				
10.3	Possibility of hazardous reactions:	No information available				
10.4	Conditions to avoid:	Heating.				
10.5	Incompatible materials:	No further relevant information available.				
10.6	Hazardous decomposition products:	No dangerous decomposition products known.				



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SECTION 11. Toxi	cological inform	nation					
11.1 Informatio	on on hazard clas	sses as define	ed in Reg	gulation	(EC) No 1272/200	8	
Acute toxi	city:						
Route of exposure:	Method	Method Species LD ₅		ose LC ₅₀ or E _{mix}	Exposure time	Results	
Oral:	oral: - rat		L	D ₅₀	-		mg/kg (ethanol) ng/kg (ethylene glycol)
Dermal:	-	rat	L	D ₅₀	-		mg/kg (ethylene glycol) g/kg (phenol)
Inhalation:	-	rat	L	C ₅₀	4 h	124.7 r	ng/l (ethanol)
Specific ta	rget organ toxic	ity – single e	xposure	(STOT S	E):		1
	Spe	cific effects			Target organ		Note
Oral:	No informatio	n available		No ir	formation availab	-	
Dermal:	No informatio	n available		No ir	No information available -		
Inhalation:	No informatio	n available	e No information availal			ole	-
Aspiration Irritation a	hazard:		No info	ormation	available.		
÷	Exposure	time Sp	ecies	Evaluatio	on Method		Note
Skin corrosion/irritation	-	in vi [.] stud		-	OECD 431	cause	es burns (phenol)
Serious eye damage/irritation	-	rabb	bit - Ol		OECD 405	corrosive (phenol)	
Sensitizati	on						
Skin sensitization:	No ir	nformation a	vailable.				
Respiratory sensitiz	ation: No ir	nformation a	vailable.				
Symptom	s related to the p	ohysical, cher	nical and	d toxicol	ogical characteris	tics	
Oral exposure:	-	tion available			•		
Dermal exposure:		tion available					
Inhalation exposure	e: No informa	tion available	e.				
Eye exposure:		tion available	e.				



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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No informatior available	ı -
Subacute dermal	No information available	No information available	No information available	No information available	No informatior available	ı -
Subacute inhalation	No information available	No information available	No information available	No information available	No informatior available	ı -
Subchronic oral	onic oral No information available No No No No information available available available available No No information available available No No information available available		ı -			
Subchronic dermal	No information available	No information available	No information available	No information available	No informatior available	ı -
Subchronic inhalation	No information available	No information available	No information available	No information available	No informatior available	ı -
Chronic oral	No information available	No information available	No information available	No information available	No informatior available	ן -
Chronic dermal No information available		No information available	No information available	No information available	No informatior available	ן -
Chronic inhalation	No information available	No information available	No information available	No information available	No informatior available	ן -
C	· · · · ·					
Specific	target organ toxicit		• •			NI-1-
		Specific effec	.15	Target o	rgan	Note

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Chronic	hronic oral No information availab			No information available -				
Chronic	Chronic dermal No information availabl		ļ	No information available -				
Chronic	Chronic inhalation No information availab			No information available -				
	1							
	CMR effects	(carcinogenicity; mutagenicit	ty; re	eproductive toxicity)				
	Carcinogenic	ity:	Bas	sed on available data, the classification criteria are not m	et.			
	Mutagenicity <i>in vitro</i> : Genotoxicity:		Bas	sed on available data, the classification criteria are not m	et.			
			Bas	sed on available data, the classification criteria are not m	et.			
	Mutagenicity in vivo:			Based on available data, the classification criteria are not met.				
	Germ cell mutagenicity:			Based on available data, the classification criteria are not met.				
	Reproductive toxicity:			Based on available data, the classification criteria are not met.				
	Summary c properties:	of evaluation of the Cl	MR	Based on available data, the classification criteria are met.	e not			
11.2	Information of	on other hazards:						
11.2.1.	Endocrine di	srupting properties:						
	No known e that affect hu	ndocrine disrupting proper Iman health.	ties					
11.2.2.	Other inform	ations:						
	-							

SECTION 12. Ecological information								
12.1 Toxicity								
Acute (short- term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		
Fish	LC ₅₀	96 hours	Leuciscus idus (Golden orfe; ethanol) Oncorhynchus mykiss (rainbow trout; phenol)	-	-	8.140 mg/l (ethanol) 72.860 mg/l (ethylene glycol) 5.0 mg/l (phenol)		
Crustacea:	EC ₅₀	48 hours	Daphnia magna (Water flea)	-	-	7.800 mg/l (ethanol) >100 mg/l (ethylene glycol) 3.1 mg/l (phenol)		



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Algae/aquatic plants	IC ₅₀	7 days	green algae	-	-	5.000 mg/l (ethanol) 6.500-13.000 mg/l (ethylene glycol) 61.1 mg/l (phenol)
Other organisms	-	-	-	-	-	-
Chronic (long- term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	-	-	-
Crustacea:	EC ₅₀	48 hours	No information available	-	-	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	-	-	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

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

Biodegradation

		1		
% Degradation	Degradation Time (days)		Evaluation	Note
94% (ethanol)	No information available	OECD 301E	No information available	readily biodegradable
85% (phenol) 14 days		OECD 301C	No information available	readily biodegradable
12.3 Bioaccum	nulative potential			
Octanol-water partition coefficient (log Kow)				
Value	Concentration pH	°C Metho	d Evaluatio	n Note



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Trading na	me:				ТВ	CARE	BOL FUG	CHSIN	REAG	ENT			
Product co	de:	TBC-C	DT-X**		Date	of co	mpilati	on:	21 De	c 2022	١	Version: 5	
-	-		-	-	-			-				accumulation expected	n is
		tration	actor (BCF)			1etho		F.				Nata	
Value No informat		No	Species inform	ation	No info				valuatio ormatio			Note	
available	lion	availab		ation	availabl		JN	availat		on	-		
Chr	ronic ec	otoxicit	у	*						*			
Va	alue		Dose	-	osure me	Sp	ecies	Met	hod	Evalu	ation	Note	9
Chronic toxi	oxicity on fish LC ₅₀ No No available available		No inform availat				-						
Chronic toxi crustacea (D)	EC ₅₀	No inforr availa	mation able	No infor avail	mation able	No inform availat		No inform availab		-	
12.4 Mo	bility in	soil								·			
			d distributi	on in e	nvironm	ental	compart	ments:					
No	inform	ation av	ailable										
Sur	face tei	nsion:											
	Value		°C	Co	oncentra	tion		Metho	bc			Note	
	ormatio iilable		ormation ailable		informat ilable	tion		No information available		-			
Ads	sorptior	n / deso	rption										
Transport	A	/D coef enry's co	ficient	lo	og Kow	E	vaporati	on rate		Method		Note	
Soil-water	No availa	in	formation	No in availa	iformatic ible		o inform vailable	ation	No ir avail	nformati able		-	
Water-air	No availa		formation	No in availa	iformatic ible		o inform vailable	ation	No ir avail	nformati able		-	



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Trading	g name:		ТВ СА	RBOL FUCHSIN	N REAGENT		
Produc	t code:	TBC-OT-X**	Date o	f compilation:	21 Dec 2022	Version:	5
Soil-air	No avail	information able	No information available	No information available	No information available	-	
12.5	Results of	PBT and vPvB asse	ssment				
12.5		available data, the		contain any PBT o	r vPvB substances.		
1				,			
12.6.	Endocrine	disrupting propert	ties				
	Based on	available data, doe	s not contain endo	ocrine disruptors.			
12.7.	Other adv	erse effects					
12.7.		r relevant informati	ion available.				
SECTIO	N 13. Disp	osal consideration	15				
13.1	Waste ti	reatment methods					
1711	Due du et						
13.1.1.		/Packaging disposa for disposal to the		rized by the Minis	stry of Environmenta	l and Nature	
	Protecti	•					
13.1.2.	Waste c	odes/waste design	ations according to	o Law:			
	15 01 1(substan		contains residual h	azardous substan	ces or is contaminate	ed with hazardo	ous
13.1.3.	Waste ti	reatment – relevant	information:				
	No info	rmation available					
13.1.4.	Sewage	disposal – relevant	information:				
		nust not be dispose		ige system.			
13.1.5.	Other d	isposal recommend	lations:				
	authoriz	• •	in charge. Do not	dispose of the pac	m. Submit the remain kaging into the sewa harge.		
13.1.6.	Relevan	t Community provi	sions:				
	Disposa	l must be made acc	cording to official r	egulations.			
			TION				



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Trading name:		TB CARBOL FUCHSIN	REAGENT		
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Transporting/shipment by road (
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (R	D)
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IN	ADG)
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-



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Trading name:			TB CARBOL FUCHSI	N REAGENT		
Product code:	TBC-OT-X**		Date of compilation:	21 Dec 2022	Version:	5
Special precautions	for user:	-				
Further information) : –					

Further information:

15.1	Safety, health and enviro	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 (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 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; 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					

SECTIO	N 16. Other information	
16.1	Indication of changes:	-



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Tradin	ng nai	me:				Т	B CAR	BOL F	UCHSI	N REAGENT			
Produ	ct co	code: TBC-OT-X** Date of compilation: 21 Dec 2022 Version:						Version:	5				
16.2	Abt	previat	ions and acron	ıyms:	route Goods IMDG: IATA: GHS: EINEC CAS:	(Euro s by I : Inte Glo CS: Eu Ch : De Let Let Pe	opean A Road) ernation ernation obally Ha ropean emical A erived Ne thal con thal dos rsistent,	greeme al Marit al Air Tr armonis Invento Abstract o-Effect icentrati ice, 50 pc Bioacc	ime Code ransport a sed System bry of Exis as Service : Level (U ion, 50 pe ercent umulative	erning the Interr e for Dangerous Association m of Classificatic sting Commercia (division of the K REACH)	Goods on and I I Chem	andises dangereu I Carriage of Dan Labelling of Cher nical Substances can Chemical Soci	igerous nicals
16.3.		literat rce of	ure references data:	and	-								
16.4.			ion and procee 8 (CLP)	dure us	ed to d	deriv	e the cl	lassifica	ation for	mixture accor	ding to	o Regulation (E	C)
Classifi	icatior	า		C	lassifica	atior	n proce	dure					
-				-									
16.5.	Rele	evant H	l statements (i	number	and fu	ull te	ext)						
		H225	5	High	y flamr	mab	le liqui	d and v	/apor.				
		H226	5	Flam	mable l	liqui	d and v	/apor.					
		H301	1	Toxic	if swal	llow	ed.						
	H:	H302	2	Harm	ful if sv	wallo	owed.						
		H311	1	Toxic	in con	ntact	with sk	kin.					
		H314	1	Caus	es seve	ere sl	kin buri	ns and	eye dan	nage.			
		H331	l	Toxic	if inha	aled.							
		H341	1	Susp	ected o	of ca	using g	genetic	defects.				
		H373	3	May	cause c	dam	age to	organs	through	n prolonged or	repea	ited exposure.	
16.6.	Trai	ning a	dvice:	-									
16.7.	** "> proc				** "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						ı		
					ctions y data s			improp	er use c	f the product o	describ	ped in this mate	erial

ANNEX: Exposure scenario resulting to chemical safety assessment

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

1.1	Product identifier							
	Trading name:	TB DECOLO	DRIZER					
	Chemical name:	-	-					
	Catalogue number:	TBD-OT-X**						
1.2	Relevant identified use	es of the subs	tance or m	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:		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 2409997					
	Telefax.:		+385 1 2	2404039				
	e-mail of competent p	erson:	<u>msds@t</u>	<u>biognost.hr</u>				
	National contact:		-					
1.4	Emergency telephone	number						
	National Protection ar	d Rescue Dire	ectorate:	112				
	Medical information:			+385 1 2348 342				
	Other information:			_				

SECTIO	SECTION 2. Hazards identification				
2.1	Classification of the substance of	or mixture			
2.1.1	Classification according to Regu	ulation (EC) No 12	272/2008 (CLP)		
	Hazard class and catego	ory code:		Hazard statements*:	
	Flam. Liq. 2 H225				
2.1.2.	Additional information				
	-				
*For ful	l text of Hazard- and EU Hazard-	statements: see S	ECTION 16		
2.2	Label elements				
	Product identification: TB DECOLORIZER				
	Identification number: -				
	Authorization number:	-			



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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 know	vn specific hazards for human or environment.
	Results of PBT and vPvB assess PBT or vPvB substances.	ment: Based on available data, the product does not contain any
	Endocrine disrupting property	Based on available data, does not contain endocrine disruptors.

SECTION 3. Composition/information on ingredients						
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)		
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- 0147	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		

SECTI	SECTION 4. First aid measures				
4.1	Description of first aid measures				
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.			
	Following inhalation:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.			



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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 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		
	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 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.			



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

 5.4
 Additional information

SECTIO	ON 6. Accidental release meas	ures			
6.1	Personal precautions, protecti	ve equipment and emergency procedures			
6.1.1.	For non-emergency personne				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.			
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:				
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.				
6.2	Environmental precautions:				
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.				
6.3	Methods and material for 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).			
6.4	Reference to other sections				
	See Section 7 for information	on safe handling.			
		on personal protection equipment.			
	See Section 13 for disposal inf	See Section 13 for disposal information.			

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



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Trading name:					
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5
				tod stars as reasons	

	Measures to prevent fire:		Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, oper 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. Th	oroughly was	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:	Manufactu	cturer's original packaging.			
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.				
	Advices for storage equipment:	The storage must be made of hard material; floors m be resistant to chemicals. There must be no drain the directly leads into sewage system. Secure propy ventilation.				
	Further information on storage conditions:	ns: Do not place the unused material in the storage roo and do not use empty containers for storing oth chemicals. Do not store with incompatible materials (s Section 10).				
7.3	Specific end use(s)					
	Recommendations:	-				
	Industrial sector specific solutions:	-				

SECTION 8. Exposure controls/personal protection								
8.1 Control parameter	Control parameters							
Substance	CAS No		exposure limit t term values	Biological limit values				
		ppm	mg/m ³					
Ethanol	64-17-5	1000/-	1900/-	-				
Hydrogen chloride	7647-01-0	5/10	8/15	-				



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Trading na	ame:					TB D	ECOLORIZER			
Product co	ode:	TBD-OT	-X**		Revisio	on date	21 Dec 2022		Version:	5
Substance r	name:	-	1						_	
EC No:		-	CAS No):	-					
DNEL										
					Ine	dustrial				
Route of		Acu			Acute		Chronic		Chronic	
exposure:		effect	local		t systemio		effect local		effect systemic	
Oral		- 1900 mg	1/m ³	-		-		-		
Inhalation	alation (ethanol)			- 380		380 mg	/m ³ (ethanol)			
Dermal	Dermal		-		343 mg	/kg (ethanol)				
Critical phys	sical para	meters: s	olubility,	flamma	ability, cor	rrosivity:	-			
					Co	nsumer				
Route of			cute		Acute		Chronic		Chronic	
exposure:		effec	t local	effec	t systemi	с	effect local		effect systemic	
Oral		-	, 2	-		-		87 mg/	kg bw/day (eth	nanol)
Inhalation		950 m (ethan	0	-		-		114 mg	/m ³ (ethanol)	
Dermal		-		-		-		206 mg	/kg (ethanol)	
PNEC										
Environmer	ntal prote	ction tar	get			PNEC				
Fresh water						0.96 m	g/l (ethanol)			
Freshwater	sediment	S				3.6 mg,	'kg (ethanol)			
Marine wate	er					0.79 m	g/l (ethanol)			
Marine sedi	iments					2.9 mg/kg (ethanol)				
Food chain						380-720 mg/kg (ethanol)				
Microorgan	isms in se	ewage tr	eatment			580 mg/l (ethanol)				
Soil (agricul	ltural)					0.63 mg/kg (ethanol)				
Air				no information available						
8.2	Exposur	e contro	ls							
8.2.1.	Approp	riate eng	ineering	control	5					
		-	ire related e during			concen concen existing	e of a hazardous r tration limit it is th tration levels down scientific and tech ous substance poses	e employ to a minir nological	ver's duty to num achievabl means, where	keep le by



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Trading name:	TB DECOLORIZER					
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	Structural measures to prevent exposure:		In accordance with Section 7.			
	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent ex	posure:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation			
	-		Use non-sparkling ventilation system.			
			Provide appropriate personal protective equipment, safety shower and eye-wash station.			
8.2.2.	Personal protection equipment					
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield ISO 16321-1:2022, EN 166).				
8.2.2.2.	Skin protection					
	Hand protection:	Use ap	appropriate, chemical-resistant protective gloves (EN 374).			
	Other skin protection:	Use appropriate protective clothing.				
8.2.2.3.	Respiratory protection:	In case of normal usage and ventilation, it is not necessar concentration of ethyl alcohol exceeds occupational exposure li in the air, use a self-contained breathing apparatus. For s contact and if the oxygen content of the air is greater than 18 % a protective 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				

SECTI	ON 9. Physical and chemical proper	ties			
9.1	Information on basic physical and chemical properties				
		Value	Method		
	Physical state:	liquid	No information available		
	Colour:	colourless	No information available		



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

Boiling p point an Flammal Lover an Flash po Auto-igr Decomp pH: Kinemat Solubility Partition octanol/ Vapour Density	nd upper explosion limit:	 No information available No information available No information available No information available 17 °C No information available 	No information available No information available No information available No information available No information available
point an Flammal Lover an Flash po Auto-igr Decomp pH: Kinemat Solubility Partition octanol/ Vapour Density	nd boiling range: bility: nd upper explosion limit: bint:	No information available No information available 17 °C	No information available No information available
Lover an Flash po Auto-igr Decomp pH: Kinemat Solubility Partition octanol/ Vapour Density	nd upper explosion limit: bint:	No information available	No information available
Flash po Auto-igr Decomp pH: Kinemat Solubility Partition octanol/ Vapour Density	bint:	17 °C	
Auto-igr Decomp pH: Kinemat Solubilit Partition octanol/ Vapour Density		-	No information available
Decomp pH: Kinemat Solubility Partition octanol/ Vapour Density	nition temperature:	No information available	
pH: Kinemat Solubilit Partition octanol/ Vapour Density		INO INFORMATION available	No information available
Kinemat Solubilit Partition octanol/ Vapour Density	oosition temperature:	No information available	No information available
Solubility Partition octanol/ Vapour Density		7.0 – 8.0 (20°C)	No information available
Partition octanol/ Vapour Density	tic viscosity:	No information available	No information available
octanol/ Vapour Density	y:	No information available	No information available
Density	n coefficient n- /water (log value):	No information available	No information available
, ,	pressure:	No information available	No information available
	and/or relative density:	No information available	No information available
Relative	vapour density:	No information available	No information available
Particle		No information available	No information available
9.2 Other in	characteristics:		

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



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	BD-OT-X**	Re	vision		OLORIZER				
	BD-OT-X**	Re	vicion						
			VISION	date:	21 Dec	2022		Version:	5
Route of exposure:	Method	Species	Dc	ose LD ₅₀ / ATE _m		Exposure t	ime	Resul	ts
Oral:	-	rat (ethanol)		LD ₅₀)	-		7.060 m	g/kg
Dermal:	-	rabbit (ethanol))	LD ₅₀)	-		>20.000	mg/l
Inhalation:	-	rat (ethanol)		LC ₅₀		4 h		>8.000	mg/l
Specific targe	t organ toxi	city – single expo	osure (S	TOT SE):					
_		ecific effects			Target or	jan		Note	
Oral: N	lo informatio	on available		No info	ormation ava	ailable	-		
Dermal: N	lo informatio	on available		No information available -					
Inhalation: N	on available		No info	ormation av	ailable	-			
Aspiration ha	zard:	Ν	o inforr	mation a	vailable.				
Irritation and	corrosion								
Intation and		ure time	Spec	ies	Evaluation	Method	4	Note	
Skin corrosion/irritation:	-	-			-	-	-		
Serious eye damage/irritation	-	-			-	-	-		
Sensitization									
Skin sensitization:	No i	nformation avail	able.						
Respiratory sensitization	on: No i	nformation avail	able.						
Symptoms re	lated to the	physical, chemica	al and t	ovicoloc	ical charact	eristics			
Oral exposure:	Absorption unconsciou	of great q usness and alcoh nay occur. Repea	uantitie ol poiso	es may oning. In	cause d case of swal	izziness, dı llowing grea	t quant	ities, nausea	
Dermal exposure:	After proto cracking of	onged or repea skin.	ted exp	oosure s	symptoms r	nay include	defat	ting, drynes	s an
Inhalation exposure:	Inhalation membrane	of great quantitie s.	es may o	cause diz	ziness, eupł	noria and mil	d irrita	tion of the m	iucou
Eye exposure:	May cause	irritation and red	dness.						



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

Specific target	organ toxicity – repeated exposure (STOT RE):	
	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-



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Trading name:	TB DECOLORIZER						
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Chronic	: inhalation	No information availabl	e		No information available	-
	CMR effects (carcinogenicity; mutagenic	itv: re	enroductive t	oxicity)	
	Carcinogenic		-	•	ble data, the classification (criteria are not met.
	Mutagenicity <i>in vitro</i> : Genotoxicity: Mutagenicity <i>in vivo</i> : Germ cell mutagenicity: Reproductive toxicity:				ble data, the classification of	
			Ba	sed on availa	ble data, the classification of	criteria are not met.
			Ba	sed on availa	ble data, the classification of	criteria are not met.
			Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.			
	Summary o properties:	f evaluation of the C	CMR	Based on a met.	available data, the classific	ation criteria are not
11.2	Information o	on other hazards:				
11.2.1.	Endocrine dis	srupting properties:				
	Based on ave endocrine dis	ailable data, does not cor sruptors.	ntain			
11.2.2.	Other inform	ations:				
	-					

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



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TBD-OT-X* LC50 EC50 IC50 - and degradation Degradation I Do information Do information	96 hours 48 hours 72 hours - ability half-lives available	Revision d No inform available No inform available No inform available Image: A state of the state	ation No inform availa ation No inform availa ation No inform availa - En No inf availa	nation ble nation ble Evaluatior	No inform available No inform available No inform available -	nation	on: 5
EC ₅₀ EC ₅₀ IC ₅₀ - e and degrada gradation Degradation I o information o information	48 hours 72 hours - ability half-lives available	available No inform available No inform available No inform available - Method No information available No information available	ation inform availa ation No ation No ation No inform availa - - En No inf availa	ble nation ble nation ble Evaluatior	available No inform available No inform available -	nation	
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o information	available	No informatio available No informatio	on No int availa	formation	ı	N	ote
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	available						
		avanubic		No information available		-	
o information	available	No informatio available		No information available		-	
o information	available	No information No information available available			n _		
ation							
	(days)	Method	I	Evaluatior	n	N	ote
		No informationavailable	on No in	formation	n No		tion
lative potenti	ial						
•		og Kow)					
oncentration	рН		ethod	Evalua	ation		Note
		-	-			•	luct does ccumulate
	ation Time No i available	Time (days) No information available lative potential ater partition coefficient (I pricentration pH	Information available available ation Time (days) Method No information available No information available lative potential Interpretion ater partition coefficient (log Kow) oncentration pH °C	Information available available ation Time (days) Method No information No information No in available available No information available available ative potential Information No information No information attive potential Information No information No information attive potential Information No information No information attive potential Information Information Information	Information available available available ation Time (days) Method Evaluation No information No information No information available available available lative potential Image: state of the state of th	Information available available available ation Time (days) Method Evaluation No information No information No information available available available available lative potential ater partition coefficient (log Kow) Method Evaluation	Information available available available ation Time (days) Method Evaluation No information available No information available No information available No information available lative potential Image: state of the s



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

			on factor (BCF)									
	Value		Species		M	ethod		Εv	aluatio	on		Note
BCF: 0	0.66 No inform available		ation	ation No information available			No information available		on	-		
	Chronic	c ecoto	kicity									
	Value		Dose	-	oosure ime	Spec	ies	Meth	od	Eva	luation	Note
Chroni	ic toxicity	on fish	LC ₅₀	No infor availa	mation	No informa availab		No informa availab		No infor availa	mation able	-
Chronic toxicity on crustacea (<i>Daphnia</i>)		EC ₅₀	No N information in		No informa availab	nformation info	No informa availab		No infor availa	mation able	-	
		ormatio	licted distributi n available n:	on in e	environme	ental co	mpartr	ments:				
	No info	ormation tension	n available		environme oncentrat		mpartr	ments: Metho	d			Note
	No info Surface	tension ue ation	n available n:	C		ion on I		Metho			-	Note
	No info Surface Valu No informa	tension ue ation	n available n: °C No information	C	oncentrat informati	ion on I	No info	Metho			-	Note
	No info Surface Valu No informa availabl	e tension ue ation le	n available n: °C No information	C	oncentrat informati	ion on I	No info	Metho			-	Note
Transp	No info Surface Valu No informa availabl Adsorp	tion / d	n available n: °C No information available	C No ava	oncentrat informati	ion I	No info availab	Metho)	Metho		Note
Transp Soil-w	No info Surface Valu No informa availabl Adsorp	tion / d	n available n: °C No information available esorption coefficient ry's constant information	C No ava	oncentrat informati iilable og Kow	ion I ion I Eva	No info availab	Metho ormation le		Metho	d	
	No info Surface Valu No informa availabl Adsorp	tion / d Alion / d Alion / d	n available n: °C No information available esorption coefficient ry's constant information ble information	C No ava	oncentrat informati iilable og Kow nformation able	ion I ion I Eva n No i avai n No i	No info availab	Metho ormation le on rate ation	No ir availa	Metho nforma able nforma	d tion tion	



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Trading name:		TB DECOLORIZER						
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.
	Haste mast hot be disposed of mee the senage system.
13.1.5.	Other disposal recommendations:
13.1.5.	Do not dispose of the product's remains into the sewage system. Submit the remains to the collector
	authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submi
	the packaging to the collectors authorized by the ministry in charge. Unused product residues may be burnt.
13.1.6.	Relevant Community provisions:
13.1.0.	
	Disposal must be made according to official regulations.
SECTIO	
	Transporting/shipment by road (ADR)
UN num	nber: 1170
UN prop	per shipping name: Ethanol solution



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Trading name:		TB DEC	OLORIZER	
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version: 5
			2	
Transport hazard cl	ass(es):	3		
Packing group:		11		
Environmentally ha	zardous:	-		
Special precautions	for user:	-		
Transporti	ng/shipment by rail (RI	D)		
UN number:		1170		
UN proper shipping	g name:	Ethanol solution		
Transport hazard cl	ass(es):	3		
Packing group:		11		
Environmentally ha	zardous:	-		
Special precautions	for user:	-		
Inland wat	erway transport (ADN)			
UN number:		1170		
UN proper shipping	g name:	Ethanol solution		
Transport hazard cl	ass(es):	3		
Packing group:		11		
Environmentally ha	zardous:	-		
Special precautions	for user:	-		
Transporti	ng/shipment by sea (IN	/IDG)		
UN number:		1170		
UN proper shipping	g name:	Ethanol solution		
Transport hazard cl	ass(es):	3		
Packing group:		ll		
Environmentally ha	zardous:	-		
Special precautions	for user:	-		
Transport in bulk a of MARPOL 73/78 a	according to Annex II and the IBC code:	-		
Transporti	ng/shipment by air (IC	AO-TI/IATA-DGR)		
UN number:		1170		
UN proper shipping	g name:	Ethanol solution		
Transport hazard cl	ass(es):	3		
Packing group:		11		
Environmentally ha	zardous:	-		
Special precautions	for user:	-		
Further information	ı: -			



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Trading name:	TB DECOLORIZER						
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 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 793/92 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 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 10 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 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	nt		
	None			

SECTION 16. Other information		
16.1	Indication of changes:	-



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Trading name:			TB DECOLORIZER				
Product code: TBD-OT-X**		TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5	
16.2	Abbreviati	ions and acronyms:	DNEL:Derived No-Effect LLC50:Lethal concentratioLD50:Lethal dose, 50 perPBT:Persistent, Bioaccur	nt Concerning the Internation ne Code for Dangerous Go nsport Association d System of Classification a y of Existing Commercial C Service (division of the Am Level (UK REACH) on, 50 percent cent	onal Carriage of Dang ods and Labelling of Chem hemical Substances	jerous licals	
16.3.	- 1	Key literature references and source of data:					
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP))		
Classification			Classification procedure -				
16.5. Relevant H statements (n		H statements (numb	mber and full text)				
	H: 2 3	225 114 335	Highly flammable liquid an Causes severe skin burns ar May cause respiratory irrita	nd eye damage.			
16.6.	Training a	dvice:	-				
16.7.	tl Further information: V ir		* "X" in the product code marks different volumes (different packagings of he product) We are not responsible for consequences in case of failure to comply with nstructions for use or improper use of the product described in this naterial safety data sheet.				

ANNEX: Exposure scenario resulting to chemical safety assessment
-



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

1.1	Product identifier					
	Trading name:	METHYLENE BLUE I		DEFFLER'S REAGENT		
	Chemical name:	-	-			
	Catalogue number:	MBL-OT-X*	MBL-OT-X**			
1.2	Relevant identified use	es of the subs	tance or n	nixture and uses advised against		
	Uses:		For stair	ning in microbiology and histology.		
	Uses advised against:		Only the identified uses are advised. Unsuitable for human comsumption.			
	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	Details of the supplier of the safety data sheet				
	Supplier:	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:	National contact:				
1.4	Emergency telephone	Emergency telephone number				
	National Protection and Rescue Dire		ectorate:	112		
				+385 1 2348 342		
	Medical information:			+385 1 2348 342		

SECTIO	N 2. Hazards identification				
2.1	Classification of the substance	or mixture			
2.1.1	Classification according to Regi	ulation (EC) No 12	272/2008 (CLP)		
	Hazard class and catego	ory code:	Hazard statements*:		
	Flam. Liq. 3		H226		
2.1.2.	Additional information				
	-				
*For ful	l text of Hazard- and EU Hazard-	statements: see S	ECTION 16		
2.2	Label elements				
	Product identification: METHYLENE BLUE LOEFFLER'S REAGENT				
	Identification number: -				
	Authorization number:	-			



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Trading name:		METHYLENE BLUE L	OEFFLER'S REAGEN	Т	
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	
	Results of PBT and vPvB assess PBT or vPvB substances.	vn specific hazards for human or environment. ment: Based on available data, the product does not contain any 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	

SECTI	SECTION 4. First aid measures			
4.1	Description of first aid measure	S		
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.		
	Following inhalation:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.		
	Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.		



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Trading name:		METHYLENE BLUE L	OEFFLER'S REAGEN	Т	
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	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	ibstance or mixture	
	Hazardous combustion products:	Highly flammable liquid and vapour. In case of fire, smoke, and other combustion products (carbon monoxide, carbon dioxide) may be formed, the inhalation of such combustion products can have serious adverse effects on health. Vapours may form an explosive mix with air. Vapours may be ignited by open flames, sparks, electrical equipment, or static charge. Vapours may travel to great distances, ignite in contact with ignition sources and flash back to the primer source (container). Vapours of ethyl alcohol mix greatly with air and may form an explosive mixture. Air containing $3.3 - 19\%$ ethyl alcohol vapours may explode in contact with ignition sources. Diluting the mixture with large amounts of water results in the loss of its flammability (around 10 % concentration of ethyl alcohol).	
5.3	Advice for firefighters		
	Wear full protective clothing and self-contained breathing apparatus. Cool the fire affected containers with water spray. Use water spray to dissipate alcohol vapours.		
5.4	Additional information		
	-		



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

6.1	Personal precautions, protective equipment and emergency procedures			
6.1.1.	For non-emergency personne			
	Protective equipment:	Use personal protective equipment (see Section 8).		
	Accident prevention methods	Evacuate members of all non-essential personnel and those members without protective equipment.		
	Emergency procedures:	Mark the area using proper signs.		
6.1.2.	For emergency responders:			
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. U spark-proof tools. Be aware of the risk of slipping.			
6.2	Environmental precautions:			
	not allow the product and the	e resulting waste according to the applicable environmental regulations. Do 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	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).		
6.4	Reference to other sections	Reference to other sections		
	See Section 7 for information	on safe handling.		
	See Section 8 for information on personal protection equipment.			
	See Section 13 for disposal int			

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



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Trading	g name:		METHYLEN	NE BLUE L	OEFFLER'S REAGEN	т			
Produc	ct code:	MBL-OT-X**	Revisio	n date:	23 Dec 2022	Version:	9		
	Measures	s to prevent fire:			away from heat, he flames and othe	ted storage rooms. Ke ot surfaces, sparks, op r ignition sources. on-sparkling tools a	pen No		
	Measure	s to prevent aerosol and	d dust generatio	on:	Ensure adequate v	entilation.			
	Measure	s to protect the environ	ment:		Prevent spilling int and waterways.	o the sewage system			
Other measures: Protect against electros				ctrostatic charges.					
7.1.2.	I.2. Advice on general occupational hygiene:								
	Do not e	at, drink or smoke in th	e workspace. Th	noroughly v	vash hands after work a	and before eating.			
7.2	Conditio	ns for safe storage, inclu	uding any incon	npatibilities	5				
	Technica	l measures and storage	conditions:	away fro unopen	a well-ventilated place, om sources of heat an ed and hermetically xidizing agents, food ption.	d ignition, in its origir sealed packaging, av	nal, way		
	Packagin	g materials:		Manufa	cturer's original packag	ing.			
	Requiren	nents for storage rooms	and vessels:	Keep av tightly o	vay from food and drin closed.	k. Keep the containers	;		
	Advices f	or storage equipment:		be resis directly	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.				
	Further ir	nformation on storage o	conditions:	and do	place the unused mate not use empty cont als. Do not store with ind 10).	ainers for storing otl	her		
7.3	Specific e	end use(s)							
	Recomm	endations:		-					
	Industria	l sector specific solutior	าร:	-					

SECTION 8. Exposure contro	SECTION 8. Exposure controls/personal protection								
8.1 Control parameters									
Substance	CAS No		exposure limit t term values	Biological limit values					
		ppm	mg/m ³	-					
Ethanol	64-17-5	1000/-	1900/-	-					
Substance name: -									



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Trading	name:			N	IETHYLE	NE BL	UE LO	EFFLER'S REA	AGENT		
Product	code:	MBL-OT	-X**		Revisic	on dat	e:	23 Dec 2022		Version:	9
TC No.											
EC No:		-	CAS No	):	-						
DNEL						J 4					
		<b>A</b>				dustria				Chanadia	
Route of exposure		Acu effect			Acute t systemic			hronic ect local		Chronic effect systemic	
Oral		-	local	-	c systemic	-	CIII		-	chect systemic	
Inhalatio	n	1900 mg (ethanol)		-		-				/m ³ (ethanol)	
Dermal		-		-		-			343 mg	/kg (ethanol)	
Critical p	hysical para	meters: s	olubility,	flamma	ability, cor	rosivity	<i>/</i> :	-		. <u> </u>	
•	<u> </u>		<u> </u>			nsume		<u> </u>			
Route of exposure			ute t local		Acute t systemic		-	hronic ect local		Chronic effect systemic	
Oral		-		-		-			87 mg/	kg bw/day (eth	anol)
Inhalatio	n	950 m (ethan	0	-		-			114 mg	/m ³ (ethanol)	
Dermal		-		-		-			206 mg	/kg (ethanol)	
PNEC											
Environm	nental prote	ection targ	get			PNEC					
Fresh wa	ter					0.96 n	ng/l (etł	nanol)			
Freshwat	er sedimen	ts				3.6 m	g/kg (et	hanol)			
Marine w	vater					0.79 n	ng/l (etł	nanol)			
Marine s	ediments					2.9 m	g/kg (et	hanol)			
Food cha	ain					380-7	20 mg/l	kg (ethanol)			
Microorg	ganisms in s	ewage tre	eatment			580 m	g/l (eth	anol)			
Soil (agri	cultural)					0.63 n	ng/kg (e	ethanol)			
Air						no inf	ormatio	n available			
8.2	Exposu	re control	S								
8.2.1.	Approp	riate engi	ineering	controls	5						
		nce/mixtu : exposure				conce conce existir	ntratior ntratior Ig scier	n limit it is th n levels down	ne employ to a minir nological	vith no contro ver's duty to k num achievabl means, where o workers.	keep e by
	Structu exposu	ral measu re:	res to pr	event		In acc	ordance	e with Section 7	7.		



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Trading	name:	I	METHYLI	ENE BLUE I	OEFFLER'S REAGEN	T				
Product	code:	MBL-OT-X**	Revisi	on date:	23 Dec 2022	Version:	9			
	Orgar expos	nisational measures to prev sure:	/ent	Organization of work in order to reduce other worker's influence during work process.						
	Techr	ical measures to prevent e	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-s	parkling ventilation syste	em.				
				Provide appropriate personal protective equipment, shower and eye-wash station.						
8.2.2.	Perso	nal protection equipment		:						
8.2.2.1.	Eye a	nd face protection:	•	Use appropriate, chemical-proof protective glasses/face shield ( ISO 16321-1:2022, EN 166).						
8.2.2.2.	Skin protection									
	Hand	protection:	Use ap	Use appropriate, chemical-resistant protective gloves (EN 374).						
	Other	skin protection:	Use ap	appropriate protective clothing.						
8.2.2.3.	Respi	ratory protection:	concer in the contac	ntration of et air, use a t and if the c	usage and ventilation hyl alcohol exceeds occ self-contained breathin xygen content of the air ask with filter A (EN 148	upational exposure ng apparatus. For is greater than 18 %	limits short			
8.2.2.4.	Thern	nal hazards:	No the	rmal hazard	s known.					
8.2.3.	Enviro	onmental exposure control	S							
		ance/mixture related ures to prevent exposure:	See Se	ction 6						
	Structural measures to prevent exposure:			Use modern equipment.						
		nisational measures to nt exposure:	Adapt the work process to the required working conditions of the workplace.							
	Techr expos	nical measures to prevent sure:	See Section 6							

SECTI	ON 9. Physical and chemical prope	rties					
9.1	Information on basic physical and chemical properties						
		Value	Method				
	Physical state:	liquid	No information available				
	Colour:	blue	No information available				
	Odour/odour threshold:	ethanol like/no information available	No information available				
	Melting point / freezing point:	No information available	No information available				



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Trading name:		METHYLENE BLUE L	OEFFLER'S REAGEN	т	
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	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
	Lover 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	DN 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. Toxic	SECTION 11. Toxicological information									
11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008										
Acute toxicity:										
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results					
Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg					
Dermal:	-	rabbit (ethanol)	LD ₅₀	-	>20.000 mg/l					



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Trading name:			ME	THYLENI	BLUE	LOEFFLER'S	REAGENT	ruge s	-	
Product code:	Μ	BL-OT-X**	1	Revision	date:	23 Dec 2	022	Versi	on:	9
Inhalation:		- rat (ethanol) LC ₅₀					4 h		>8.000 r	ng/l
Specific	targe	t organ toxicit	y – single ex	posure (S	TOT SE):					
		Spec	ific effects			Target organ	ı	١	Vote	
Oral:	N	o information	available		No info	ormation avail	able -			
Dermal:	N	o information	available		No info	ormation avail	able -			
Inhalation:	Ν	o information	available		No info	ormation avail	able -			
8										
Aspirati	on haz	zard:		No inform	mation a	vailable.				
Irritation	n and	corrosion		_				1		
		Exposur	e time	Spec	ies	Evaluation	Method		Note	
Skin corrosion/irritation	on.	-		-		-	-	-		
Serious eye										
damage/irritation	n	-		-		-	-	-		
Sensitiz										
Skin sensitization			ormation av							
Respiratory sensi	itizatic	on: No inf	ormation av	ailable.						
Sumpto	mc rol	atad ta tha ph	weical cham	vical and t	ovicalaa	ical characteri	cticc			
Sympto	ins rei	ated to the ph Absorption	•	quantitie	-			kenness,	eupho	oria.
Oral exposure:		unconscious	ness and alco	ohol poise	oning. In	case of swallor ed exposure m	wing great qu	uantities,	nausea	,
Dermal exposure	2:	After prolon cracking of s		eated exp	oosure s	ymptoms ma	y include: d	efatting,	drynes	s and
Inhalation expos	ure:	Inhalation of membranes.	great quanti	ties may o	ause diz	ziness, eupho	ria and mild ir	rritation c	of the m	ucous
Eye exposure:		May cause ir	ritation and	redness.						
Repeate	ed dos	e toxicity (sub	acute, subcł	nronic, chi	onic)	1			1	
		Dose	Exposure time	Speci	es	Method	Evaluatio	on	Note	
Subacute oral		information lable	No information available	No n inforn availa	nation ble	No information available	No infor available		_	



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Trading name:		METH	HYLENE BLUE	LOEFFLER'S R	EAGENT		
Product code:	MBL-OT-X** Re		evision date:	23 Dec 2022		Version:	9
Subacute dermal	No information available	No information available	No information available	No information available	No informa available	tion _	
Subacute inhalation	No information available	No information available	No information available	No information available	No informa available	tion _	
Subchronic oral	No information available	No information available	No information available	No information available	No informa available	tion _	
Subchronic dermal	No information available	No information available	No information available	No information available	No informa available	tion _	
Subchronic inhalation	No information available	No information	No information	No information	No informa available	tion _	

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No

No

No information

No information

No information

available

available

available

Chronic oral

Chronic dermal

Chronic

inhalation

Specific targe	et organ toxicity – repeated exposure	e (STOT RE):	
	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal No information available		No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-



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Trading	g name:		METHYL	ENE BLUE I	LOEFFLER'S REAGEN	IT			
Produc	Product code: MBL-OT-X**			on date:	23 Dec 2022	Version:	9		
	Mutageni	city <i>in vitro</i> :	Bas	sed on availa	ble data, the classificati	ion criteria are not n	net.		
	Genotoxicity:		Bas	ed on availa	ble data, the classificati	ion criteria are not n	net.		
	Mutagenicity in vivo:		Bas	sed on availa	ble data, the classificati	ion criteria are not n	net.		
	Germ cell mutagenicity:		Bas	ed on availa	ble data, the classificati	ion criteria are not n	net.		
	Reproductive toxicity:		Bas	Based on available data, the classification criteria are not met.					
	Summary propertie		the CMR	Based on a met.	available data, the clas	sification criteria ar	e not		
11.2	Informatio	on on other hazards:							
11.2.1.	Endocrine	e disrupting properties:							
		available data, does not contain e disruptors.							
11.2.2.	Other info	ormations:							
	-								

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



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-ode.								
Product code: MBL-OT-X**		*	Revision date:		23 Dec 2022		Vers	ion:
uatic plant	nts IC ₅₀ 72 hours		No information available		intormation		_	
anisms	-	-	-		-	-		-
Abiotic de	gradation	-		Method				Jote
laring water I No intermation available				No informationavailable	on -	-		
Fresh water No informa		available	-		No informatio available		-	
Air No infor		available	No information available		No information available		-	
oil No information available		available	No information available		No information available		-	
		No information			No information available			ation
	•		log Ko	DW)				
	oncentration	рН	°C	Method	Eval	uation		Note
~ -		-	-	-	-		•	duct does accumulate
<u>le</u>	•			nformation			-	Note
	Persistence Abiotic deg ater No er No Biodegrada radation hation Bioaccumu Dctanol-w e C a	Persistence and degrada Abiotic degradation Degradation h ater No information er No information No information Biodegradation radation Time ( hation No in available Bioaccumulative potention Concentration of Patient Speci Bioconcentration factor of ue Speci No in	Image: Image	Justic plants       IC50       72 hours       a         Janisms       -       -       -       -         Persistence and degradability       Abiotic degradation       No       No       avai         Abiotic degradation       Degradation half-lives       No i       No i         ater       No information available       No i       No i         ater       No information available       No i       avai         No information available       No i       avai       No i         Biodegradation       Time (days)       Integradation       avai         Biodegradation       No information available       avai         Biodegradation       Time (days)       Integradation         ation       No information available       avai         Bioaccumulative potential       Avai         Dotanol-water partition coefficient (log Kore       Concentration       PH         C       -       -       -         Bioconcentration factor (BCF)       Integration       Integration         No       information       No information       No information         No       information factor (BCF)       Integration       No information         No       information       <	Jatic plants       ICso       72 hours       available         anisms       -       -       -         Persistence and degradation       -       -       -         Abiotic degradation       Degradation half-lives       Method         ater       No information available       No information available       No information available         er       No information available       No information available       No information available         No information available       No information available       No information available         No information available       No information available       No information available         Biodegradation       Time (days)       Method         radation       No information available       No information available         Bioaccumulative potential       No information available       No information available         Bioaccumulative potential       pH       °C       Method         ~       -       -       -       -         Bioaccumulative potential       pH       °C       Method         ~       -       -       -       -         Bioaccumulative potential       -       -       -       -         PH       °C       Method	Datic plants       IC ₅₀ 72 hours       No information available       information available         anisms       -       -       -       -       -         Persistence and degradability       Abiotic degradation       Method       Evaluation         Abiotic degradation       Degradation half-lives       Method       Evaluation available         Abiotic degradation       No information available       No information available       No information available         ater       No information available       No information available       No information available       No information available         er       No information available         No information available       No information available       No information available       No information available         Biodegradation       Time (days)       Method       Evaluation available         Bioaccumulative potential       No information available       No information available       No information available         Bioaccumulative potential       Image: Potential       Image: Potential       Image: Potential       Image: Potential         Concentration       pH       °C       Method       Evaluation <t< td=""><td>uatic plants     IC₅₀     72 hours     No information available     information available     No information available       anisms     -     -     -     -     -       Persistence and degradability     Method     Evaluation     -       Abiotic degradation     Degradation half-lives     Method     Evaluation     -       ater     No information available     No information available     No information available     No information available     No information available     No information available     -       er     No information available     No information available     No information available     No information available     No information available     -       No information available     No information available     No information available     No information available     -       Biodegradation ataion     Time (days)     Method     Evaluation     -       Bioaccumulative potential     No information available     No information available     -     -       Bioaccumulative potential     pt     *C     Method     Evaluation       Concentration     pH     *C     Method     Evaluation       ~     -     -     -     -       Bioconcentration factor (BCF)     _     -     -       No     information</td><td>Jatic plants       ICso       72 hours       No information available       information available       No information available         anisms       -       -       -       -       -         Persistence and degradability       Degradation half-lives       Method       Evaluation       No         Abiotic degradation       Degradation half-lives       Method       Evaluation       No         ater       No information available       No information available       No information available       No information available       No information available       -         No information available       No information available       No information available       No information available       -       -         No information available       No information available       No information available       No information available       -       -         Biodegradation       Time (days)       Method       Evaluation       No information available       No information available       No information available       No information available       No information available         Bioaccumulative potential       Concentration       pH       °C       Method       Evaluation       The pro not bios         Concentration       pH       °C       Method       Evaluation       The pro not bios     </td></t<>	uatic plants     IC ₅₀ 72 hours     No information available     information available     No information available       anisms     -     -     -     -     -       Persistence and degradability     Method     Evaluation     -       Abiotic degradation     Degradation half-lives     Method     Evaluation     -       ater     No information available     No information available     No information available     No information available     No information available     No information available     -       er     No information available     No information available     No information available     No information available     No information available     -       No information available     No information available     No information available     No information available     -       Biodegradation ataion     Time (days)     Method     Evaluation     -       Bioaccumulative potential     No information available     No information available     -     -       Bioaccumulative potential     pt     *C     Method     Evaluation       Concentration     pH     *C     Method     Evaluation       ~     -     -     -     -       Bioconcentration factor (BCF)     _     -     -       No     information	Jatic plants       ICso       72 hours       No information available       information available       No information available         anisms       -       -       -       -       -         Persistence and degradability       Degradation half-lives       Method       Evaluation       No         Abiotic degradation       Degradation half-lives       Method       Evaluation       No         ater       No information available       No information available       No information available       No information available       No information available       -         No information available       No information available       No information available       No information available       -       -         No information available       No information available       No information available       No information available       -       -         Biodegradation       Time (days)       Method       Evaluation       No information available       No information available       No information available       No information available       No information available         Bioaccumulative potential       Concentration       pH       °C       Method       Evaluation       The pro not bios         Concentration       pH       °C       Method       Evaluation       The pro not bios



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Trading name:		METHYLENE BLUE L	OEFFLER'S REAGENT		
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	Chronic			Exposure	<u> </u>		<b>.</b>		_		
	Value		Dose	time	Spe	ecies	Meth	nod	Εv	aluation	Note
Chronic toxicity on fish LC ₅₀		LC ₅₀	information	No inforn availa	nation ble	No informa availab			rmation ilable	-	
	c toxicity cea ( <i>Daph</i>		EC ₅₀	information	No inforn availa	nation ble	No informa availab		_	rmation lable	-
12.4	Mobilit	y in soi	il								
	Known	or pree	dicted distributi	on in environme	ental c	ompart	ments:				
	No info	ormatio	n available								
	Surface	e tensio	n:								
	Valı	Je	°C	Concentrat	ion		Metho	d			Note
			No information available	No information available		No information - available -			-		
	Adsorp		desorption								
Transp	ort		D coefficient ary's constant	log Kow	Ev	Evaporation rate			Meth	od	Note
Soil-wa	ater	No availa	information able	No information available				No information available		ation .	-
Water-	ter-air No information available		No information available		No information available		No information available		ation	-	
Soil-air	Soil-air No information available		No information available		No information No info available availab			ation	-		
12.5			and vPvB asses		+ - · ·		DDT		In		
	Based o	on avai	lable data, the p	product does no	τ conta	ain any	PRIOLA	PVB SU	ostar	ices.	
12.6.	Endocr	ine disi	rupting properti	es							
	1										



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Trading name:		METHYLENE BLUE I	OEFFLER'S REAGEN	IT	
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 th 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	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 recomme					
	authorized by the minist	roduct's remains into the sewage system. Submit the remains to the collectors ry 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	road (ADR)				
UN num	ıber:	1170				
UN proj	per shipping name:	Ethanol solution				
Transpo	rt hazard class(es):	3				
Packing	group:	III				
Environ	mentally hazardous:	-				
Special	precautions for user:	-				
	Transporting/shipment by	rail (RID)				
UN num	nber:	1170				



Product code: UN proper shipping Transport hazard cla Packing group: Environmentally haz Special precautions Inland wate UN number:	ass(es):	Revision date: Ethanol solution 3	23 Dec 2022	Version:	9		
Transport hazard cla Packing group: Environmentally haz Special precautions Inland wate	ass(es):	3					
Transport hazard cla Packing group: Environmentally haz Special precautions Inland wate	ass(es):	3					
Packing group: Environmentally haz Special precautions Inland wate							
Environmentally haz Special precautions Inland wate		111					
Special precautions Inland wate	zardous:	-					
1		-					
1	erway transport (ADN)						
UN Humber.		1170					
UN proper shipping	name:	Ethanol solution					
Transport hazard cla	ass(es):	3					
Packing group:		III					
Environmentally haz	zardous:	-					
Special precautions	for user:	-					
Transportin	ng/shipment by sea (IN	/DG)					
UN number:		1170					
UN proper shipping	name:	Ethanol solution					
Transport hazard cla	ass(es):	3					
Packing group:		III					
Environmentally haz	zardous:	-					
Special precautions	for user:	-					
Transport in bulk ac of MARPOL 73/78 a	ccording to Annex II nd the IBC code:	-					
Transportin	ng/shipment by air (IC	AO-TI/IATA-DGR)					
UN number:		1170					
UN proper shipping	name:	Ethanol solution					
Transport hazard class(es):		3					
Packing group:		III					
Environmentally haz	zardous:	-					
Special precautions	for user:	-					
	1	rovision 144 – An aqueou					

#### **SECTION 15. Regulatory information**

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



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

	EU regulations					
	Authorization and/or rest	rictions of use				
	Authorizations:	-				
	Restrictions:	-				
	Other EU regulations:	<ul> <li>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;</li> <li>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 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;</li> <li>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;</li> <li>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).</li> <li>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</li> </ul>				
	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					

SECTIO	ON 16. Other information	
16.1	Indication of changes:	-



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Turali			B 4				
Trading name:			METHYLENE BLUE LOEFFLER'S REAGENT				
Product code:		MBL-OT-X**		Revision date:	23 Dec 2022	Version:	9
16.2	Abbreviati	ons and acronyms:	route Good IMDC IATA: GHS: EINEC CAS: DNEL LC50: LD50 PBT:	DNEL:Derived No-Effect Level (UK REACH)LC50:Lethal concentration, 50 percentLD50:Lethal dose, 50 percent			
16.3.	Key literature references and source of data:		Manufacturer's MSDS file.				
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)						2)
Classification		Classification procedure					
-		-					
16.5.	Relevant H statements (number and full text)						
	H: 2	25	Highly flammable liquid and vapour.				
	226		Flammable liquid and vapour.				
16.6.	Training a	dvice:	-				
16.7.	Further information:		the pro We are instruct	"* "X" in the product code marks different volumes (different packagings of he product) We are not responsible for consequences in case of failure to comply with nstructions for use or improper use of the product described in this material safety data sheet.			

#### ANNEX: Exposure scenario resulting to chemical safety assessment

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