

TB-STAIN HOT KIT

The kit contains:

TB Carbol Fuchsin reagent TB Decolorizer Methylene Blue Loeffler reagent



Page 1 of 18

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

SECTI	ON 1: Identification of t	he substance	e/mixture	e and of the company/undertaking	
1.1	Product identifier				
	Trading name:	TB CARBOL	FUCHSIN	REAGENT	
	Chemical name:	-			
	Catalogue number:	TBC-OT-X**			
1.2	Relevant identified use	s of the subst	ance or n	nixture and uses advised against	
	Uses:		For use	in TB-Stain Cold, TB-Stain Hot kit and TB-Stain Quick kits.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses advis	sed against: The product is intended for use only as an <i>in vitro</i> diagnostic med device, registered at the Agency for Medicinal Products and Med 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 +385 1 2404039 <u>msds@biognost.hr</u>		
	Telefax.:				
	e-mail of competent p	erson:			
	National contact:		-		
1.4	Emergency telephone	number			
	National Protection an	d Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ECTION 2. Hazards identification				
2.1	Classification of the substance or mixture				
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)				
	Hazard class and category code:	Hazard statements*:			
	Flam. Liq. 3	H226			
	Muta. 2	H341			
	Acute Tox. 3	H331			
	Acute Tox. 3	H311			
	Acute Tox. 3	H301			
	Skin. Corr. 1B	H314			
	STOT RE 2	H373			
2.1.2.	Additional information				
	-				
*For fu	ill text of Hazard- and EU Hazard-statements: se	ee SECTION 16			



Page 2 of 18

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

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



Page 3 of 18

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

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	

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 ef	fects, both acute and delayed		



Page 4 of 18

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

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

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 su	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 of	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.	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:				



Page 5 of 18

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

	Do not let product enter drai	ns. Risk of explosion.
6.3	Methods and material for cor	ntainment and cleaning up
6.3.1.	Bunding, covering of drains; capping procedures:	Cover drains. Collect, bind, and pump off spills.
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 See Section 8 for information See Section 13 for disposal in	on personal protection equipment.

SECTIO	DN 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 generatio	n:	Secure proper ventilation.
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.
	Other measures:		Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:		
	Do not eat, drink or smoke in the workspace. Th	oroughly was	h 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	rer's original packaging.
	Requirements for storage rooms and vessels:	Keep away tightly clos	from food and drink. Keep the containers red.



Page 6 of 18

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

	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/persc	onal protec	tion				
8.1 Control pa	arameters							
Substance		CA	S No			exposure limit term values		Biological limit values
				рр	m	mg/m³		-
Ethanol		64	-17-5	100	0/-	1900/-		-
Ethylene glycol		107	7-21-1	20/	40	52/104		
Phenol		108	8-95-2	2/	<i>'</i> 4	8/16	mo	mg/g of creatinine (0.14 /mol of creatinine), end of t, urinary excretion
Substance name:	-	1						
EC No:	-	CAS No): -					
DNEL								
			•	Indu	strial			
Route of exposure:	Acu effect		Acut effect sys			Chronic effect local		Chronic effect systemic
Oral	-		-		-			-
Inhalation	1900 mg (ethanol)		-		35 mg (ethyle	/kg ene 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			



Page 7 of 18

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

Route of exposure		Acute effect local	Acute effect system	Chronic ic effect local	Chronic effect systemic	
Oral		-	-	-	87 mg/kg (ethanol) 0.5 mg/kg (phenol)	
Inhalatio	n	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						
Environm	nental protec	ction target		PNEC		
Fresh wa	ter			0.96 mg/l (ethanol) 10 mg/l (ethylene glyco 0.0077 mg/l (phenol)	ol)	
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 s	ediments			2.9 mg/kg (ethanol) 3.7 mg/kg (ethylene glycol) 0.00915 mg/kg (phenol)		
Food cha	ain			380-720 mg/kg (ethan	ol)	
Microorg	ganisms in se	ewage treatment		580 mg/l (ethanol) 199.5 mg/l (ethylene glycol) 2.1 mg/l (phenol)		
Soil (agri	cultural)			0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene g 0.136 mg/kg (phenol)	glycol)	
Air				no information availab	le	
0.2	-					
8.2	•	e controls	an utur la			
8.2.1.	Appropr	riate engineering	controls		Lucentileted as easy they are an	
		ce/mixture relate exposure during		•	l ventilated rooms. Use personal Do not eat, drink or smoke in the	

workspace.

prevent exposure during identified uses:



Page 8 of 18

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

	Structural measures to prevent exposure:		In accordance with Section 7.
Organisational measures to prever exposure:		ent	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent ex	exposure: Secure proper workspace ventilation in order to kee exposure: concentration levels in air below permitted levels. Se stations for rinsing eyes and showering.	
8.2.2.	Personal protection equipment		
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of low levels of concentration in air; protective gas mask that covers t entire face in case of higher levels of concentration in air.	
8.2.2.2.	Skin protection		
	Hand protection:	Regula Full co	otective gloves have to satisfy the specification of tition (EU) 2016/425 and the related standard EN 374. ntact: 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:	footwe entire imperr	everyday work use cotton clothing (EN 340) and suitable ear, such as rubber boots (EN 20345) or shoes that cover the foot. In case of spilling hazard, use clothing made of neable material suitable for protection from liquid chemicals 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 mo	odern equipment.
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.
	Technical measures to prevent exposure:	See Se	ction 6



Page 9 of 18

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

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				
Lower 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.				



Page 10 of 18

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

SECTION 11. Toxic	ological info	ormation						
11.1 Information	n on hazard o	lasses as	defined i	in Regu	lation (E	C) No 1272/200	8	
Acute toxic	ity:							
Route of exposure:	Method	Spec	cies	Dos LD ₅₀ /LC ATE _n	S ₅₀ or l	Exposure time		Results
Oral:	-	ra	t	LD ₅	0	-		mg/kg (ethanol) ng/kg (ethylene glycol)
Dermal:	-	ra	t	LD ₅	0	-		mg/kg (ethylene glycol) g/kg (phenol)
Inhalation:	-	ra	t	LC ₅₀	0	4 h	124.7 n	ng/l (ethanol)
÷								
Specific tar	get organ to	xicity – si	ngle expo	osure (S	TOT SE):			1
	S	pecific ef	fects			Target organ		Note
Oral:	No informa	tion avail	able		No info	rmation availab	le	-
Dermal:	No informa	tion avail	able		No info	rmation availab	le	-
Inhalation:	No informa	tion avail	able		No info	rmation availab	le	-
					<u> </u>			
Aspiration	hazard:		N	lo infori	mation av	vailable.		
Irritation a	nd corrosion							
	Exposu	re time	Specie	es Ev	/aluation	Method		Note
Skin corrosion/irritation:	-		in vitro study	-		OECD 431	cause	es burns (phenol)
Serious eye damage/irritation	-		rabbit	-		OECD 405	corro	sive (phenol)
Sensitizatio	n							
Skin sensitization:	1	informa	tion avail	able				
Respiratory sensitiza			tion avail					
, , ,		-						
Symptoms	related to th	e physica	ll, chemic	al and t	oxicolog	ical characterist	ics	
Oral exposure:	No infor							
Dermal exposure:	No inform							
Inhalation exposure		nation av						
I	_							



Subchronic inhalation

No information available

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

Page 11 of 18

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

	Dose	Exposure time	Species	Method	Evaluatior	n Note
Subacute oral	No information available	No information available	No information available	No information available	No informatic available	on -
Subacute dermal	No information available	No information available	No information available	No information available	No informatic available	on -
Subacute inhalation	No information available	No information available	No information available	No information available	No informatic available	on -
Subchronic oral	No information available	No information available	No information available	No information available	No informatic available	on -
Subchronic dermal	No information available	No information available	No information available	No information available	No informatic available	on -
Subchronic inhalation	No information available	No information available	No information available	No information available	No informatic available	on -
Chronic oral	No information available	No information available	No information available	No information available	No informatic available	on -
Chronic dermal	No information available	No information available	No information available	No information available	No informatic available	on -
Chronic inhalation	No information available	No information available	No information available	No information available	No informatic available	on -
Coocific	targat argan tavisit	v ropested a				
specific	target organ toxicit	· ·	•		raan	Note
Subacute oral	No informa	Specific effec	.15	Target o No information	-	-
Subacute dermal		ation available		No information		-
Subacute inhalat		tion available		No information		-
Subchronic oral		tion available		No information available		-
Subchronic derm		tion available		No information		-
<u> </u>						

No information available

-



Page 12 of 18

Trading	name:	TB CARBOL FUCHSIN REAGENT							
Product code:		TBC-OT-X**	** Date of compilation:		n:	21 Dec 2022	Version:	5	
Chronic c	oral	No information	available	N	lo in	formation available	_		
Chronic c	dermal	No information	available	Ν	lo in	formation available	-		
Chronic i	nhalation	No information	available	Ν	lo in	formation available	-		
		ts (carcinogenicity; m		•					
	Carcinoge					ta, the classification c			
	Mutagenio	city in vitro:	Bas	Based on available data, the classification criteria are not met.					
	Genotoxic	ity:	Bas	Based on available data, the classification criteria are not met.					
	Mutagenio	tity <i>in vivo</i> :	Bas	Based on available data, the classification criteria are not met.					
(Germ cell	mutagenicity:	Bas	Based on available data, the classification criteria are not met.					
	Reproduct	ive toxicity:	Ba	Based on available data, the classification criteria are not met.					
	Summary properties		the CMR	Based on ava met.	ailab	le data, the classifica	ation criteria a	are not	
11.2	Informatic	n on other hazards:							
	Endocrine	:							
	No knowr	n endocrine disruptin human health.							
11.2.2.	Other info	rmations:							
	-								

SECTION 12. Ed	SECTION 12. Ecological information									
12.1 Toxicity	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)				



Page 13 of 18

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

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

Abiotic degradation	
---------------------	--

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

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
94% (ethanol)	No information available	OECD 301E	No information available	readily biodegradable
85% (phenol)	14 days	OECD 301C	No information available	readily biodegradable
12.3 Bioaccumu	lative potential			
Octanol-w	ater partition coefficient (log Kow)		
Value C	oncentration pH	°C Metho	d Evaluatio	n Note



Page 14 of 18

Trading	namo:				TRO						10	ige 14 of 18	5
Product		TBC-OT-X** Date of compi									١	Version:	
riouuci	coue.	TDC-V	J1-X		Date		пріац	511.	21 De	C 2022	Ň		5
-	-		-	-				-				accumulation expected	n is
	Bioconcer	ntration	factor (BCF)										
Va	lue		Species		M	ethoo	ł	E١	aluatio	on		Note	
No infor available		No availat	inform	ation	No infor available		on	No info availab		on	-		
	Chronic e	cotoxicit	.y										
	Value		Dose		osure me	Spe	ecies	Meth	nod	Evalu	ation	Note	9
Chronic toxicity on fish LC ₅		LC ₅₀	information		No infori availa	mation able	No inform availab		No inform availab		-		
Chronic toxicity on crustacea (<i>Daphnia</i>)		EC ₅₀	No information available			lo No nformation inform vailable availa			No inform availab		-		
12.4	Mobility i	n soil											
	Known or No inform	-	ed distributi vailable	on in e	environme	ntal c	compart	ments:					
	Surface te												
	Value		°C	Co	oncentrati	on		Metho	d			Note	
	No informatio available		o ormation ailable		informati ilable	on	No inf availal	ormation ble	n	-			
	Adsorptio	n / desc	orption										
Transpoi	rt	A/D coef enry's co		lo	og Kow	E١	vaporati	on rate		Method		Note	
Soil-wate	er No avail		nformation	No in availa	nformatior able		o inform ⁄ailable	nation	No ir availa	nformatio able	on -	-	
Water-ai	ir No avail		nformation	No in availa	nformatior able		o inform vailable	nation	No ir availa	nformatio able	on -	-	



Page 15 of 18

				ARBOL FUCHSI		Page 15 of 1	0		
Trading	g name:								
Produc	t code:	TBC-OT-X**	Date of	compilation:	21 Dec 2022	Version:	5		
Soil-air	No availa	information able	No information available	No information available	No information available	_			
12.5	Results of	PBT and vPvB asse	ssment						
	Based on a	available data, the _l	product does not o	contain any PBT o	r vPvB substances.				
12.6.	Endocrine	disrupting propert	ies						
	Based on a	available data, does	s not contain endo	ocrine disruptors.					
12.7.	Other adv	erse effects							
	No furthe	r relevant informati	on available.						
		osal consideration	IS						
13.1	Waste tr	eatment methods							
13.1.1.	Product,	/Packaging disposa	ıl:						
	Submit f Protectio	•	egal person autho	rized by the Minis	stry of Environmenta	l and Nature			
13.1.2.	Waste co	odes/waste designa	ations according to	o Law:					
	15 01 10 substanc		ontains residual h	azardous substan	ces or is contaminate	ed with hazardo	ous		
13.1.3.	Waste tr	reatment – relevant	information:						
	No infor	mation available							
13.1.4.	Sewage	disposal – relevant	information:						
		nust not be dispose		ge system.					
13.1.5.	Other di	sposal recommend	lations:						
	authoriz	• •	in charge. Do not o	dispose of the pa	m. Submit the remain ckaging into the sew narge.				
	Relevant Community provisions:								
13.1.6.									
13.1.6.		l must be made acc		egulations.					



Page 16 of 18

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

Transporting/shipment by road (ADR)
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	Ш
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (R	ID)
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	MDG)
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:	-



Page 17 of 18

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

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture							
	EU regulations							
	Authorization and/or rest	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 an Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/9 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EE 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 200 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 amendin Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safet 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 1 December 2008 on classification, labelling and packaging of substances and mixture amending and repealing Directives 67/548/EEC and 1999/45/EC, and amendin Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certaid dangerous substances, mixtures and articles (Annex XVII); 						
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC- guideline)							
	gardenine) Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values an 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							
	None	· · · · · · · · · · · · · · · · · · ·						

SECTION 16. Other information					
16.1	Indication of changes:	-			



Page 18 of 18

Trading name:					TB CARBOL FUCHS	IN RE	AGENT			
Product code: TBC-OT-X**			TBC-OT-X**		Date of compilation:	21	Dec 2022	Version:	5	
16.2 Abbreviations and acronyms:				yms:	 ADR: Accord relatif au transport international des marchandises dangereuses route (European Agreement Concerning the International Carriage of Dangero Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemical EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative 					
16.3.	· · · ·	literat rce of	ure references data:	and	-					
16.4.		sificati 2/2008	•	lure use	ed to derive the classification fo	or mixt	ure according t	o Regulation (E	C)	
Classifi	icatior	۱		Cl	assification procedure					
-				-						
16.5.	Rele	evant H	l statements (n	number	and full text)					
		H225		Highl	y flammable liquid and vapor.					
		H226	5	Flamr	Flammable liquid and vapor.					
		H301		Toxic	xic if swallowed.					
	H:	H302		Harm	armful if swallowed.					
		H311		Toxic	in contact with skin.					
		H314	ļ	Cause	es severe skin burns and eye da	mage.				
		H331		Toxic	if inhaled.					
		H341		Suspe	ected of causing genetic defect	5.				
		H373		May o	ause damage to organs throug	jh pro	longed or repea	ated exposure.		
16.6.	Trai	ning a	dvice:	-						
16.7.	Furt	ther inf	formation:	produ We ar instru	in the product code marks diff act) re not responsible for conseque ctions for use or improper use data sheet.	ences i	n case of failure	e to comply with	n	

ANNEX: Exposure scenario resulting to chemical safety assessment

_



Page 1 of 17

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

SECTI	ON 1: Identification of t	the substance	e/mixture	and of the company/undertaking			
1.1	Product identifier	Product identifier					
	Trading name:	TB DECOLO	RIZER				
	Chemical name:	-					
	Catalogue number:						
1.2	Relevant identified use	es of the subst	tance or n	nixture and uses advised against			
	Uses:		For use	in TB-Stain Cold and TB-Stain Hot kit.			
	Uses advised against:		Only the	e identified uses are advised.			
	Reason why uses advised against:		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 2404039				
	e-mail of competent p	erson:	msds@biognost.hr				
	National contact:		-				
1.4	Emergency telephone	number					
	National Protection an	d Rescue Dire	ectorate:	te: 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 Reg	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 DECOLORIZE	R						
	Identification number:	-							
	Authorization number:	-							



Page 2 of 17

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

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

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



Page 3 of 17

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

4.3	Following ingestion: Indication of any immediate medi	Ingestion of larger quantities may affect the central nervous system. cal attention and special treatment needed				
	Following eye contact:	May irritate the eyes.				
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.				
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.				
4.2	Most important symptoms and ef	Most important symptoms and effects, both acute and delayed				
	Self-protection of the first aider:	-				
	Following ingestion:	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.				
	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. Place the victim in a comfortable position. Rinse the mouth with clean				
	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.				

SECTIO	ECTION 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.				



Page 4 of 17

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

 5.4
 Additional information

6.1	Personal precautions, protective equipment and emergency procedures					
6.1.1.	For non-emergency personnel					
0.1.1.	Protective equipment:	Use personal protective equipment (see Section 8).				
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members				
	Emergency procedures:	Mark the area using proper signs.				
6.1.2.						
	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, ignit and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area 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 cont	ainment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.				
6.3.2.	Cleaning up:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).				
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).				
6.4	Reference to other sections					
	See Section 7 for information on safe handling.					
	See Section 7 for information of	on sale handling.				
		on personal protection equipment.				

SEC	SECTION 7. Handling and storage				
7.1		Precautions for safe handling			
7.1	.1.	Protection measures			



Industrial sector specific solutions:

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

Page 5 of 17

						Page 5 of 1	7	
Trading name:		TB DECOLORIZER						
Product code:		TBD-OT-X**	TBD-OT-X** Revision date:		21 Dec 2022 Version:		5	
	Measures	to prevent fire:	fire:		Use in well ventilated storage rooms. Kee away from heat, hot surfaces, sparks, ope flames and other ignition sources. N smoking. Use non-sparkling tools an equipment.			
Measures to prevent aerosol and dust ge		dust generatior	ו:	Ensure adequate ve	entilation.			
	Measures to protect the environment: Other measures:		nent:	Prevent spilling into the sewage system and waterways.				
				Protect against electrostatic charges.				
7.1.2.	Advice or	n general occupational hy	ygiene:					
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.							
7.2	Conditions for safe storage, including any incompatibilities							
	Technical	measures and storage c	onditions:	Store in a well-ventilated place, protected from sunligh away from sources of heat and ignition, in its origina unopened and hermetically sealed packaging, awa from oxidizing agents, food, feed and articles of consumption.				
	Packaging	g materials:		Manufacturer's original packaging.				
	Requirem	heeps for storage rooms and vessels.			Keep away from food and drink. Keep the containers tightly closed.			
			The stora			rage must be made of hard material; floors must tant to chemicals. There must be no drain that		

	Advices for storage equipment:	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:	-

_

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/-	-			
Hydrogen chloride	7647-01-0	5/10	8/15	-			



				-	-		Page 6 of 17
Trading na	me:				TB DE	COLORIZER	
Product co	de:	TBD-01	Г-X**	Revisi	on date:	21 Dec 202	22 Version: 5
Substance n	name:	-		ł			
EC No:		-	CAS No): -			
DNEL							
				In	dustrial		
Route of		Αςι	ute	Acute		Chronic	Chronic
exposure:		effect	local	effect systemi	ic	effect local	effect systemic
Oral		-		-	-		-
Inhalation		1900 mg (ethanol	-	-	-		380 mg/m ³ (ethanol)
Dermal		-		-	-		343 mg/kg (ethanol)
Critical phys	sical par	ameters:	solubility,	flammability, co	rrosivity:	-	
				Co	onsumer		
Route of		A	cute	Acute		Chronic	Chronic
exposure:		effe	ct local	effect system	ic	effect local	effect systemic
Oral		-		-	-		87 mg/kg bw/day (ethanol)
Inhalation		950 m (ethar	-	-	-		114 mg/m ³ (ethanol)
Dermal		-		-	-		206 mg/kg (ethanol)
PNEC					-		
Environmen	tal prot	ection tar	get		PNEC		
Fresh water					0.96 mg/	'l (ethanol)	
Freshwater s	sedimer	nts			3.6 mg/k	g (ethanol)	
Marine wate	er				0.79 mg/	'l (ethanol)	
Marine sedi	ments				2.9 mg/k	g (ethanol)	
Food chain					380-720	mg/kg (ethanol)	
Microorgani	isms in s	sewage tr	eatment		580 mg/	(ethanol)	
Soil (agricul	tural)				0.63 mg/	'kg (ethanol)	
Air					no inforr	nation available	
8.2	Exposu	ire contro	ls				
8.2.1.	•	oriate eng		controls			
	Substa	nce/mixtu	ure related	d measures to identified uses:	concentr concentr	ation limit it is a ation levels dowr	material with no controlled the employer's duty to keep n to a minimum achievable by chnological means, where the

hazardous substance poses no harm to workers.



Page 7 of 17

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

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

SECTIO	N 9. Physical and chemical propert	ies	
9.1	Information on basic physical and cl	nemical properties	
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available



Page 8 of 17

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

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

SECTIO	SECTION 10. Stability and reactivity				
10.1	Reactivity:	See Section 10.5.			
10.2	Chemical stability:	Stable within normal temperature and general work conditions.			
10.3	Possibility of hazardous reactions:	See Section 10.5.			
10.4	Conditions to avoid:	Keep away from heat, sparks, open flames, strong heating and ignition sources. No smoking.			
10.5	Incompatible materials:	Strong oxidizing agents (inorganic strong acid, nitric acid, perchlorates, peroxy compounds, perchloric acid, permanganates etc.), alkali metals, alkali earth metals.			
10.6	Hazardous decomposition products:	Carbon monoxide and carbon dioxide.			

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



Page 9 of 17

						Page 9 o	
Trading name:			TB DEC	OLORIZE	R		
Product code:	TBD-OT-X*	* Rev	Revision date:		21 Dec 2022		5
Route of exposure:	Method	Species	Dose LD ₅₀ /I ATE _{mi}		Exposure tin	ne Re	sults
Oral:	-	rat (ethanol)	LD ₅₀		-	7.060	mg/kg
Dermal:	-	rabbit (ethanol)	LD ₅₀		-	>20.0	00 mg/l
Inhalation:	-	rat (ethanol)	LC ₅₀		4 h	>8.0	00 mg/l
Specific ta	rget organ to	kicity – single expos	sure (STOT SE).				
		pecific effects		Target o	rgan	Note	
Oral:		tion available	No info	rmation a	-	-	
Dermal:	No informat	tion available	No info	rmation a	vailable	-	
Inhalation:	No informat	tion available	No info	rmation a	vailable	-	
Aspiration	hazard:	No	information av	vailable.			
Irritation a	ind corrosion		<u> </u>	F 1 <i>i</i>			
Chin	Expo	osure time	Species	Evaluatic	on Method	Not	e
Skin corrosion/irritation	-	-		-	-	-	
Serious eye	_	_		_	-	_	
damage/irritation							
Sensitizati	on						
		information availa	ble.				
Skin sensitization:	Nc	information availat information availat					
Skin sensitization: Respiratory sensitiz	Nc ation: Nc	information availa	ble.				
Skin sensitization: Respiratory sensitiz	ation: No	n information availat e physical, chemical	ble. I and toxicolog				
Skin sensitization: Respiratory sensitiz Symptome	s related to the Absorptic unconscie	information availa	ble. I and toxicolog antities may I poisoning. In	cause case of sw	dizziness, dru allowing great d	quantities, nau	iphoria, sea and
Skin sensitization: Respiratory sensitiz Symptome Oral exposure:	s related to the Absorptic unconscie vomiting	e physical, chemical on of great qu ousness and alcoho may occur. Repeate	ble. I and toxicolog antities may I poisoning. In ed or prolonge	cause case of sw d exposur	dizziness, dru allowing great o re may lead to	quantities, nau liver cirrhosis.	sea and
Skin sensitization: Respiratory sensitiz	s related to the Absorption vomiting After pro- cracking	e physical, chemical on of great qu ousness and alcoho may occur. Repeate olonged or repeate of skin.	ble. I and toxicolog antities may I poisoning. In ed or prolonge ed exposure s	cause case of sw d exposur ymptoms	dizziness, dru allowing great o re may lead to may include:	quantities, nau liver cirrhosis. defatting, dry	sea and ness an



Page 10 of 17

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

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

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



Page 11 of 17

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

Chronic	inhalation	No information av	ailable	No information available -				
	CMR effects (c	arcinogenicity; muta	genicity; re	productive toxicity)				
	Carcinogenicit	y:	Bas	sed on available data, the classification criteria are not met.				
	Mutagenicity <i>i</i>	in vitro:	Bas	sed on available data, the classification criteria are not met.				
	Genotoxicity:		Bas	sed on available data, the classification criteria are not met.				
	Mutagenicity i	in vivo:	Bas	sed on available data, the classification criteria are not met.				
	Germ cell mut	agenicity:	Bas	Based on available data, the classification criteria are not met.				
	Reproductive t	toxicity:	Bas	Based on available data, the classification criteria are not met.				
	Summary of properties:	evaluation of th	ne CMR	Based on available data, the classification criteria are not met.				
	<u>L</u>							
11.2	Information or	n other hazards:						
11.2.1.	Endocrine disr	upting properties:						
	Based on avail endocrine disr	ilable data, does no ruptors.	t contain					
11.2.2.	Other information	tions:						
	-							

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



Page 12 of 17

Product code: Fish		D-OT-X**		Rov					
Fish			Product code: TBD-OT-X**		Revision date: 21 D		21 Dec 2022 V		sion: 5
		LC ₅₀	96 hours		information ailable	No information available	No inf availal	ormation ble	-
Crustacea:		EC ₅₀	48 hours		information ailable	No information available	No inf availal	ormation ble	-
Algae/aquatic pla	plants IC ₅₀ 72 hours			information ailable	No		formation ble	-	
Other organisms	, ,	-	-	-		-	-		-
12.2 Persister Abiotic o	degrad	d degradab ation radation ha	-		Vethod	Evaluati	on		Note
Marine water		ormation a			formation	No information available		-	
Fresh water	No info	lo information available		No inf availal	formation ble	No information available		-	
Air	No info	ormation a	vailable	No inf availal	information No information ilable available		on	-	
Soil	No info	ormation a	vailable	No information No information available available		on	-		
Biodegr	adatior	ı				1			
% Degradation		Time (d			Method	Evaluation		Note	
No information available	N av	o inf vailable	ormation	No information available		No information available		No information available	
12.3 Bioaccur	mulativ	e potential							
		partition co							
Value	Conce	entration	рН	°C	Method	Eva	uation		Note
Log Pow: ~ 0.32	-				-	-		The pro bioaccu	oduct does no Imulate



Page 13 of 17

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

	Biocono	entratio	n factor (BCF)							1		
	Value		Species		N	lethod	E١	aluati	on		Note	
BCF: 0.	.66	No avai	inform lable	ation	No info available		No info availab		on	-		
	Chronic	ecotoxi	city									
	Value		Dose		osure me	Species	Meth	od	Eva	aluation	Note	
Chroni	ic toxicity	on fish	LC ₅₀	No infor availa	mation able	No information available	No inform availab		No infor avail	mation able	-	
	ic toxicity cea (<i>Daph</i>		EC ₅₀	No infor availa	mation able	No information available	No informa availab		No infor avail	mation able	-	
	No info	•	cted distributi available	on in e	environme	ental compar	tments:					
	Valu	Je	°C	C	oncentrat	tion	Metho	d			Note	
	No informa		No nformation		informat	ion No in	formatio	า		_		
	availabl		available		ilable	availa	ble					
					ilable	availa	ble					
	availabl	e i			ilable	availa	ble					
Transp	Adsorp	e a tion / de A/D	available		ilable og Kow	Evaporat			Metho		Note	
Transp Soil-wa	Adsorp	e a tion / de A/D	available sorption coefficient 's constant information	lc	og Kow Iformatio	Evaporat	ion rate		nforma	od	Note	
	Adsorp oort ater	e a tion / de A/D Henry No	sorption coefficient 's constant information le information	lc No ir availa	og Kow Iformatio Ible Iformatio	Evaporat n No informavailable	ion rate nation	No ir avail	nforma able nforma	od ation -	Note	



Page 14 of 17

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:
15.1.2.	Packaging that contains residual hazardous substances or is contaminated with hazardous substances
	Fackaging that contains residual hazardous substances of is containinated with hazardous substances
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit
	the packaging to the collectors authorized by the ministry in charge. Unused product residues may be
	burnt.
13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.
SECTIO	N 14 TRANSPORT INFORMATION
	Transporting/shipment by road (ADR)
UN num	1170
UN prop	ber shipping name: Ethanol solution



Page 15 of 17

Trading name:		TB DEC	COLORIZER		
Product code: T	BD-OT-X**	Revision date:	21 Dec 2022	Version:	5
Transport hazard class	s(es):	3			
Packing group:		II			
Environmentally hazar	rdous:	-			
Special precautions fo	or user:	-			
Transporting	/shipment by rail (RI	D)			
UN number:		1170			
UN proper shipping n	ame:	Ethanol solution			
Transport hazard class	s(es):	3			
Packing group:		11			
Environmentally hazar	rdous:	-			
Special precautions fo	or user:	-			
Inland water	way transport (ADN)				
UN number:		1170			
UN proper shipping n	ame:	Ethanol solution			
Transport hazard class	s(es):	3			
Packing group:		II			
Environmentally hazar	rdous:	-			
Special precautions fo	or user:	-			
Transporting,	/shipment by sea (IN	/IDG)			
UN number:		1170			
UN proper shipping n	iame:	Ethanol solution			
Transport hazard class	s(es):	3			
Packing group:		Ш			
Environmentally hazar	rdous:	-			
Special precautions fo	or user:	-			
Transport in bulk accord of MARPOL 73/78 and		-			
Transporting,	/shipment by air (IC/	AO-TI/IATA-DGR)			
UN number:		1170			
UN proper shipping n	ame:	Ethanol solution			
Transport hazard class	s(es):	3			
Packing group:		II			
Environmentally hazar	rdous:	-			
Special precautions fo	or user:	-			
Further information:	-				



Page 16 of 17

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

Safety, health ar	d environmental regulations/legislation specific for the substance or mixture						
EU regulations	EU regulations						
Authorization ar	nd/or restrictions of use						
Authorizations:	-						
Restrictions:	-						
Other EU regula	 Regulation (EC) No 1907/2006 of the European Parliament and of the Cou 18 December 2006 concerning the Registration, Evaluation, Authorisation Restriction of Chemicals (REACH), establishing a European Chemicals A amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 1 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/76 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 Apr on the limitation of emissions of volatile organic compounds due to the use of c 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 of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council December 2008 on classification, labelling and packaging of substances and mi amending and repealing Directives 67/548/EEC and 1999/45/EC, and ame Regulation (EC) No 1907/2006; COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Parliament and of the Council Regulation (EC) No 1907/2006 of the European Pa						
	REACH Restrictions on the manufacturing, placing on the market and use of dangerous substances, mixtures and articles (Annex XVII);						
Information according	ording 1999/13/EC about limitation of emissions of volatile organic compounds (VOC						
National legislat	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values ion: on biological limit values, Regulation on categories, types and classificat of waste with a waste catalog and list of hazardous waste, Ordinance of writing Material safety data sheet, Transport of Hazardous Substances						
Chemical safety	assessment						

SECTION 16. Other information				
16.1	Indication of changes:	-		



Page 17 of 17

Trading name: Product code: TBD-OT-X**			TB DECOLORIZER			
		TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5
16.2	Abbreviations and acronyms		ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative			
16.3.	Key litera source of	ture references and data:	-			
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)					
Classification			Classification procedure			
16.5.	Relevant H statements (number and full text)					
	H: 2	225 314 335	Highly flammable liquid ar Causes severe skin burns a May cause respiratory irrita	nd eye damage.		
16.6.	Training a	advice:	-			
16.7.	Further information:		** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with nstructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to chemical safety assessment

_



Page 1 of 17

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

1.1	Product identifier					
	Trading name:	METHYLEN	E BLUE LO	EFFLER'S REAGENT		
	Chemical name:	-				
	Catalogue number:	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 comsum	e identified uses are advised. Unsuitable for human aption.		
	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:	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	number				
	National Protection ar	nd Rescue Dire	ectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:					

SECTIO	N 2. Hazards identification			
2.1	Classification of the substand	ce or mixture		
2.1.1	Classification according to R	egulation (EC) No 1	272/2008 (CLP)	
	Hazard class and cate	egory code:	Hazard statements*:	
	Flam. Liq. 3 H226			
2.1.2.	Additional information			
	-			
*For ful	l text of Hazard- and EU Hazar	rd-statements: see S	ECTION 16	
2.2	Label elements			
	Product identification: METHYLENE BLUE LOEFFLER'S REAGENT			
	Identification number: -			
	Authorization number:	-		



Page 2 of 17

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

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

SECTION 3. Co	SECTION 3. Composition/information on ingredients					
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)		
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- 0147	10 – 20 %	ethanol	Flam. Liq. 2; H225		

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



Page 3 of 17

Trading name:		METHYLENE BLUE I	OEFFLER'S REAGEN	T	
Product code:	MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9

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

SECTIO	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	bstance 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 sipate alcohol vapours.
5.4	Additional information	
	-	



Page 4 of 17

Trading name:		METHYLENE BLUE	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 personnel			
	Protective equipment:	Use personal protective equipment (see Section 8).		
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.		
	Emergency procedures:	Mark the area using proper signs.		
6.1.2.	For emergency responders:			
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Us 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 re not allow the product and the resulting waste to enter sewers/soil/surface or ground wat respective authorities in accordance with local law in the case of environmental pollution im			
6.3	Methods and material for cont	ainment and cleaning up		
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.		
6.3.2.	Cleaning up:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).		
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).		
6.4	Reference to other sections	Reference to other sections		
	See Section 7 for information of	on safe handling.		
	See Section 8 for information on personal protection equipment.			

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



Page 5 of 17

Trading name:	METHYLENE BLUE LOEFFLER'S REAGENT									
Product code:	MBL-OT-X**	Revisior	date:	23 Dec 2022	Version: 9					
Measures	to prevent fire:			away from heat, h flames and othe	ted storage rooms. Kee ot surfaces, sparks, ope r ignition sources. N on-sparkling tools an					
Measures	to prevent aerosol and	d dust generatio	n:	Ensure adequate v	entilation.					
Measures	Measures to protect the environment:			Prevent spilling int and waterways.	o the sewage system					
Other mea	Other measures:			Protect against ele	ctrostatic charges.					
7.1.2. Advice on	general occupational	hygiene:								
Do not ea	t, drink or smoke in th	e workspace. Th	oroughly v	wash hands after work a	and before eating.					
7.2 Condition	s for safe storage, incl	5								
Technical	measures and storage	conditions:	away fr unopen	om sources of heat an ed and hermetically xidizing agents, fooc	, protected from sunligh d ignition, in its origina sealed packaging, awa l, feed and articles c					
Packaging	materials:		Manufa	cturer's original packag	jing.					
Requirem	ents for storage room	s and vessels:	Keep av tightly o	-	y from food and drink. Keep the containers					
Advices fo	or 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 inf	formation on storage	conditions:	and do	not use empty cont als. Do not store with in	erial in the storage roor ainers for storing othe compatible materials (se					
7.3 Specific er	nd use(s)									
Recomme	ndations:		-							
Industrial	sector specific solution	ns:	-							

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



						_				Page 6 of	17
Trading na	ime:				METHYLE	NE BLUI	E LOE	EFFLER'S REA	GENT		
Product co	ode:	MBL-OT	Г-Х**		Revisio	on date:		23 Dec 2022		Version:	9
							1				
EC No:		-	CAS No):	-						
DNEL											
				1	Inc	dustrial			1		
Route of		Αсι			Acute			nronic		Chronic	
exposure:		effect	local	effe	ect systemic	2	effe	ct local		effect systemic	2
Oral			, 2	-		-			-		
Inhalation		1900 mg (ethanol)		-		-			380 m	g/m ³ (ethanol)	
Dermal	-	-		-		-			343 m	g/kg (ethanol)	
Critical phy	sical para	meters: s	olubility,	flamm	nability, cor	rosivity:		-			
					Co	nsumer					
Route of		A	cute		Acute		Ch	nronic		Chronic	
exposure:		effec	t local	effe	ect systemic	C	effe	ct local		effect systemic	2
Oral		-		-		-			87 mg	/kg bw/day (et	hanol)
Inhalation		950 m (ethan	0	-		-			114 m	g/m ³ (ethanol)	
Dermal		-		-		-			206 m	g/kg (ethanol)	
PNEC											
Environmer	ntal prote	ction tar	get			PNEC					
Fresh water						0.96 mg/	l (eth	anol)			
Freshwater	sediment	S				3.6 mg/k	g (eth	nanol)			
Marine wat	er					0.79 mg/	l (eth	anol)			
Marine sedi	iments					2.9 mg/k	g (eth	nanol)			
Food chain						380-720	mg/k	g (ethanol)			
Microorgan	isms in se	ewage tr	eatment			580 mg/l	(etha	anol)			
Soil (agricul	tural)					0.63 mg/	kg (et	thanol)			
Air						no inform	natior	n available			
8.2	Exposur	e contro	ls								
8.2.1.	Approp	riate eng	ineering	contro	ls						
			ire related e during			concentr concentr existing	ation ation scient	hazardous m limit it is the levels down t tific and techr ostance poses n	e emplo o a min nological	yer's duty to imum achievat means, wher	keep ole by
	Structur exposur		ires to pr	event		In accord	lance	with Section 7.			



Page 7 of 17

Trading I	name:	Γ	METHYLENE BLUE LOEFFLER'S REAGENT								
Product	code:	MBL-OT-X**	Revisi	Version:	9						
	Orgar expos	nisational measures to prev sure:	ent	Organization of work in order to reduce other worker's influence during work process.							
	Techn	ical measures to prevent e	xposure:	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 mothods and with adoguate ventilation							
				Provide ap	parkling ventilation syste propriate personal prot d eye-wash station.		fety				
8.2.2.	Perso	nal protection equipment									
8.2.2.1.	Eye ar	nd face protection:		propriate, ch 321-1:2022,	nemical-proof protective EN 166).	e glasses/face shield	(EN				
8.2.2.2.	Skin p	protection									
	Hand	protection:	Use ap	ppropriate, chemical-resistant protective gloves (EN 374).							
	Other	skin protection:	Use ap	propriate pro	otective clothing.						
8.2.2.3.	Respi	ratory protection:	concer in the contac	ntration of et air, use a t and if the o	usage and ventilation hyl alcohol exceeds occ self-contained breathi xygen content of the ai ask with filter A (EN 148	upational exposure l ng apparatus. For s r is greater than 18 %	imits short				
8.2.2.4.	Therm	nal hazards:	No the	rmal hazards	s known.						
8.2.3.	Enviro	onmental exposure controls	5								
		ance/mixture related ures to prevent exposure:	See Section 6								
	Struct expos	tural measures to prevent sure:	Use modern equipment.								
		nisational measures to nt exposure:	Adapt workpl		ocess to the required wo	orking conditions of	the				
	Techn expos	ical measures to prevent sure:									

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



Page 8 of 17

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

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

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



Page 9 of 17

Trading name:			MET	HYLENI	BLUE	LOEFFLER'S	REAGENT	ruge		
Product code:		1BL-OT-X**	R	levision	date:	23 Dec 2	022	Vers	ion:	9
Inhalation:		-	rat (ethanol)		LC ₅₀)	4 h		>8.000 n	ng/l
Specific	c targe	t organ toxicit	y – single exp	oosure (S	TOT SE)	:				
•		Spec	ific effects			Target orgar	1		Note	
Oral:	Ν	lo information	available		No info	ormation availa	able -	1		
Dermal:	Ν	lo information	available		No info	ormation availa	able -			
Inhalation:	Ν	lo information	available		No info	ormation availa	able -			
Aspirat	ion ha	zard [.]		No inforr	mation a	wailable				
, opnac		2010.								
Irritatio	on and	corrosion								
		Exposur	e time	Spec	es	Evaluation	Method		Note	
Skin		-		-		-	-	-		
corrosion/irritati	ion:									
Serious eye damage/irritatio	n	-		-		-	-	-		
Sensitiz										
Skin sensitizatio			ormation ava							
Respiratory sens	sitizatio	on: No inf	ormation ava	ilable.						
Sympto	oms re	lated to the nh	ovsical chemi	ical and t	ovicolor	gical characteri	stics			
Jynpic		•	of great					ikenness,	eupho	oria,
Oral exposure:		unconscious	ness and alco	hol poise	oning. In	case of swallor ed exposure m				and
Dermal exposure	e:	After prolon cracking of s		ated exp	oosure s	symptoms ma	y include: d	lefatting,	dryness	s and
Inhalation expos	sure:	Inhalation of membranes.	great quantit	ties may o	ause diz	zziness, euphoi	ia and mild i	rritation	of the m	ucous
Eye exposure:		May cause ir	ritation and r	edness.						
Repeat	ed dos	se toxicity (sub		ronic, chr	onic)					
		Dose	Exposure time	Specie	es	Method	Evaluatio	on	Note	
Subacute oral		information lable	No information available	No inforn availa		No information available	No infor available		-	



inhalation

available

available

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

available

					Р	age 10 of 1	7
Trading name:		METI	HYLENE BLUE	LOEFFLER'S R	EAGENT		
Product code:	MBL-OT-X**	Re	evision date:	23 Dec 202	22	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 available	No information available	No information available	No informa available	tion _	
Chronic oral	No information available	No information available	No information available	No information available	No informa available	tion _	
Chronic dermal	No information available	No information available	No information available	No information available	No informa available	tion _	
Chronic	No information	No information	No information	No information	No informa	tion _	

	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	_

available

available



Page 11 of 17

Trading name:		METHYLENE BLUE LOEFFLER'S REAGENT									
Produc	Product code: MBL-OT-X**		Revisi	on date:	Version:	9					
	Mutageni	city <i>in vitro</i> :	Bas	sed on availa	ble data, the classificati	on criteria are not r	net.				
	Genotoxicity: Mutagenicity <i>in vivo</i> : Germ cell mutagenicity:		Bas	sed on availa	ble data, the classificati	on criteria are not r	net.				
			Bas	Based on available data, the classification criteria are not met.							
			Bas	sed on availa	ble data, the classificati	on criteria are not r	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 a	re not				
11.2	Informati	on on other hazards:									
11.2.1.	Endocrine	e disrupting properties:									
		available data, does n e disruptors.	ot contain								
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	-					



Page 12 of 17

Trading name:					METHYLENE BLUE LOEFFLER'S REAGENT						
Produ	ct code:	1	MBL-OT-X**		F	Revision date:	23 Dec 20)22	Vers	ion:	9
Algae/aquatic plants IC ₅₀		IC ₅₀	72 hours		No information available	No information available		nformation _ able _			
Other o	organisms	5	-	-		-	-	-		-	
12.2	Persiste	ence a	and degradab	ility							
	Abiotic	degr	adation		1		1				
		D	egradation ha	alf-lives		Method	Evaluatio			Note	
Marine	water	No	information a	vailable	-	information ailable	No informatio available	n -			
Fresh v	vater	Noi	information a	vailable		information ailable	No informatio available	n -			
Air	No information availa		vailable		information ailable	No informatio available	n -				
Soil	No information available			vailable	No information available		No information available				
	Biodegi	radat	ion				1	3			
% De	egradatio	n	Time (c	lays)	Method		Evaluation		Note		
No info availab	ormation lle		No inf available			o information ailable	No informatio available		o inform ⁄ailable	ation	
12.3	Bioaccu	imula	ative potential								
	Octano	l-wat	er partition co	pefficient (log l	Kow)		1			
	alue	Cor	ncentration	рН	°C	Method	Evalu	uation		Note	
Log Po 0.32	₩: ~	-		-	_	-	-		The pro bioaccu	duct doe Imulate	s not
	Biocopy	entr	ation factor (E								
١	/alue		Specie	-		Method	Evaluat	ion		Note	
BCF: 0.0			•	ormation		information ailable	No informat available				



Page 13 of 17

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

	Chronie		Dose	Exposure	Sn		Meth	and and	E.	aluation	Note
	value		Dose	time		ecies		lou		aluation	Note
Chroni	c toxicity	on fish	LC ₅₀	No information available	No infori availa	mation able	No inform availab			rmation ilable	-
	c toxicity cea (<i>Daph</i>		EC50	No information available	No infori availa	mation able	No inform availab		-	rmation ilable	-
12.4	Mobilit	y in soi	I								
	Known	or pred	dicted distributi	on in environm	ental o	compart	ments:				
	No info	ormatio	n available								
	Surface	e tensio	n:								
	Val	ue	°C	Concentra	tion	on Method				Note	
	information in		No information available	No informatio available		tion No information available		า		-	
Transp		A/[lesorption D coefficient ry's constant	log Kow		vaporati	on rate		Meth	od	Note
Soil-wa	ater	No availa	information able	No information available		No information available		No information available			-
Water-	air	No availa	information able	No informatic available		No information available		No information available		ation	-
Soil-air	-	No availa	information ble	No informatio available		n No information No inf available availa			ation	-	
12.5	Results	of PBT	and vPvB asses	ssment							
	Based o	on avai	able data, the p	product does no	ot cont	ain any	PBT or v	PvB su	bstar	nces.	
12.6.	Endocr	ine disr	upting properti	es							
				not contain en							



Page 14 of 17

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

12.7.	Other adverse effects	
	Do not let the product or it	s residues reach sewer system, waterways and soil.
SECTIO	N 13. Disposal consideration	ons
13.1	Waste treatment method	S
13.1.1.	Product/Packaging dispo	sal:
	Submit for disposal to the Protection.	e legal person authorized by the Ministry of Environmental and Nature
13.1.2.	Wasto codos (wasto dosis	nations according to Lawr
13.1.2.		nations according to Law:
	Packaging that contains i	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 nun	nber:	1170
UN pro	per shipping name:	Ethanol solution
Transpo	ort hazard class(es):	3
Packing		III
	mentally hazardous:	-
Special	precautions for user:	-
	Transporting/shipment by	
UN nun	nber:	1170



п f 17

					Page 15 of 1	/			
Trading name:		METHYLENE BLUE LOEFFLER'S REAGENT							
Product code:	MBL-OT-X**		Revision date:	23 Dec 2022	Version:	9			
UN proper shippi	ng name:	Eth	anol solution						
Transport hazard	class(es):	3							
Packing group:		111							
Environmentally hazardous:		-							
Special precautions for user:		-							
Inland w	aterway transport (Al	DN)							
UN number:		1170							
UN proper shippi	ng name:	Ethanol solution							
Transport hazard	class(es):	3							
Packing group:		III							
Environmentally h	nazardous:	-							
Special precaution	ns for user:	-							
Transpor	ting/shipment by sea	a (IMDG)						
			70						

	-,
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	Ш
Environmentally hazardous:	-
Environmentally hazardous: Special precautions for user:	-
·	

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

SECTIO	ON 15. Regulatory information	
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	



Page 16 of 17

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

022

Version:

9

	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 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). 			
		REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);			
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC- guideline)				
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act			
15.2	Chemical safety assessment				
	None				

SECTION 16. Other information			
16.1	Indication of changes:	-	



Page 17 of 17

Trading name: Product code: MBL-0			METHYLENE BLUE LOEFFLER'S REAGENT						
		MBL-OT-X**	Revision date:	23 Dec 2022	Version:	9			
16.2	Abbreviations and acronyms:		ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative						
16.3.	Key litera source of	ture references and data:	Manufacturer's MSDS file.						
16.4.		Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)							
		Classification procedure							
			-						
16.5.	Relevant	H statements (numb	ber and full text)						
	H: 225 226		Highly flammable liquid and vapour.						
			Flammable liquid and vapour.						
16.6.	Training advice:		-						
16.7.	Further information:		** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with nstructions for use or improper use of the product described in this material safety data sheet.						

ANNEX: Exposure scenario resulting to chemical safety assessment