

### TB-STAIN COLD KIT

The kit contains:

TB Carbol Fuchsin reagent

TB Decolorizer

TB Malachite Green reagent



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

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

1.1	Product identifier				
	Trading name:	TB CARBOL	FUCHSIN	REAGENT	
	Chemical name:	-			
	Catalogue number:	TBC-OT-X**	ŧ		
1.2	Relevant identified use	es of the subst	tance 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 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:	Telephone number:		+385 1 2409997	
	Telefax.:		+385 1 2404039		
	e-mail of competent p	erson:	msds@biognost.hr		
	National contact:	National contact:			
1.4	Emergency telephone	Emergency telephone number			
	National Protection ar	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	

SECTIO	SECTION 2. Hazards identification				
2.1	Classification of the substance or mixture				
2.1.1	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			



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



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**Endocrine Disrupting Properties:** 

No known endocrine disrupting properties

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

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610- 43-0147	10 - 20 %	ethanol	Flam. Liq. 2; H225
107-21-1/ 203-473-3/ 603-027-00-1	-	10 - 20 %	ethylene glycol	Acute Tox. 4; H302
108-95-2/ 203-632-7/ 604-001-00-2	01-2119471329- 32-xxxx	4 -5 %	phenol	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Skin Corr. 1B; H314 Muta. 2; H341 STOT SE 2; H373

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



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

SECTION	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Water, foam, dry powder, CO <sub>2</sub>			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the su	ubstance or mixture			
	Hazardous combustion products:	Mixture with combustible ingredients. Forms explosive mixtures with air at elevated temperatures. Development of hazardous combustion gases or vapours possible in the event of fire. Vapours are heavier than air and may spread along floors.			
5.3	Advice for firefighters				
	Use a self-contained open-circuit	compressed air breathing apparatus and fireproof clothing.			
5.4	Additional information				
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do no contaminate the environment with extinguishing media.				

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



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	Do not let product enter drains. Risk of explosion.				
6.3	Methods and material for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:  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 on safe handling.				
	See Section 8 for information	on personal protection equipment.			
	See Section 13 for disposal in	formation.			

SECTIO	ON 7. Handling and storage			
7.1	Precautions for safe handling			
7.1.1.	Protection measures			
	Measures to prevent fire:		Use in well ventilated storage rooms. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge. Do not smoke.	
	Measures to prevent aerosol and dust generation	Measures to prevent aerosol and dust generation:		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.	
	Other measures:		Protect against electrostatic charges.	
7.1.2.	Advice on general occupational hygiene:			
	Do not eat, drink or smoke in the workspace. The	oroughly was	sh hands after work and before eating.	
7.2	Conditions for safe storage, including any incom	patibilities		
	Technical measures and storage conditions:	well ventila	phtly closed and upright set containers in a ated storage rooms at temperatures ranging 25 °C. Protect from heat and direct sunlight.	
	Packaging materials:	Manufactu	ırer's original packaging.	
	Requirements for storage rooms and vessels:	Keep away	r from food and drink. Keep the containers sed.	



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

SECTION 8. Expos	ure contr	ois/perso	nai prote	ction				
8.1 Control pa	arameters							
Substance	<b>!</b>	CA	S No			exposure limit term values	Biolo	gical limit values
				pp	om	mg/m³		
Ethanol		64	-17-5	100	00/-	1900/-		-
Ethylene glycol		107	'-21-1	20/	/40	52/104		
Phenol		108	3-95-2	2/	/4	8/16		of creatinine (0.14 creatinine), end of y excretion
Substance name:	-							
EC No: - C		CAS No	o: -					
DNEL								
				Indu	strial			
Route of exposure:	Acı effect		Acu effect sy			Chronic effect local		Chronic effect systemic
Oral	-		-		-		-	
Inhalation	1900 mg (ethanol	•	-		35 mg/ (ethyle	/kg ne glycol)		g/m³ (ethanol) m³ (phenol)
Dermal	-		-		-		106 m	g/kg (ethanol) g/kg (ethylene glycol ng/kg (phenol)
Critical physical par	rameters:	solubility,	flammabil	ity, corro	sivity:	-		
				Cons	umer			



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Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic		
Oral		,		87 mg/kg (ethanol)		
Oral	-	-	-	0.5 mg/kg (phenol)		
Inhalation	950 mg/ m³ (ethanol)	-	7 mg/kg (ethylene glycol)	114 mg/m³ (ethanol) 0.452 mg/m³ (phenol)		
				206 mg/kg (ethanol)		
Dermal	-	-	-	0.5 mg/kg (phenol)		
				53 mg/kg (ethylene glycol)		
PNEC						
Environmental protection	ction target		PNEC			
			0.96 mg/l (ethanol)			
Fresh water			10 mg/l (ethylene glycol)			
			0.0077 mg/l (phenol)			
			3.6 mg/kg (ethanol)			
Freshwater sediment	S		37 mg/kg (ethylene glycol)			
			0.09125 mg/kg (phenol)			
Marina			0.79 mg/l (ethanol)			
Marine water			1 mg/l (ethylene glycol) 0.00077 mg/l (phenol)			
			<del>-</del>			
Marine sediments			2.9 mg/kg (ethanol) 3.7 mg/kg (ethylene glycol)			
Marine seaments			0.00915 mg/kg (phenol)			
Food chain			380-720 mg/kg (ethanol)			
			580 mg/l (ethanol)			
Microorganisms in se	ewage treatment		199.5 mg/l (ethylene glycol)			
<b>.</b>			2.1 mg/l (phenol)			
			0.63 mg/kg (ethanol)			
Soil (agricultural)			1.53 mg/kg (ethylene glycol)			
_			0.136 mg/kg (phenol)			
Air			no information available			
8.2 Exposure	e controls					
8.2.1. Appropr	riate engineering (	controls				
	ce/mixture related exposure during i		Use the product in well vent protective equipment. Do no workspace.	-		



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	Structural measures to prevent exposure:		In accordance with Section 7.		
	Organisational measures to prevent exposure:		Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent ex	Secure proper workspace ventilation in order to ke exposure: concentration levels in air below permitted levels. Stations for rinsing eyes and showering.			
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	levels	glasses that stick to face (EN 166) or visor in case of lower of concentration in air; protective gas mask that covers the face in case of higher levels of concentration in air.		
8.2.2.2.	Skin protection				
	Hand protection:	Regula Full co Splash	Glove material: butyl rubber Glove thickness: 0.70 mm Break through time: > 480 min contact: Gloves material: nitrile rubber Glove thickness: 0.40 mm Break through time: > 120 min		
	Other skin protection:	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 meable 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 m	odern equipment.		
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.		
	Technical measures to prevent exposure:	See Se	ction 6		



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Information on basic physical and o	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  No information available		
Lower and upper explosion limit:	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		
рН:	No information available	No information available		
Kinematic viscosity:	No information available	No information available		
Solubility:	No information available	No information available		
Partition coefficient n-octanol/water (log value):	No information available	No information available		
Vapour pressure:	No information available	No information available		
Density and/or relative density:	No information available	No information available		
Relative vapour density:	No information available	No information available		
Particle characteristics:	No information available	No information available		

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



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11.1 Information	ological infor		defined in	Regu	lation (F(	C) No 1272/200	<u></u> 8	
Acute toxic		3303 43	defined in	ricgu	iation (Et	2) 110 1272/200	<u> </u>	
Route of exposure:	Method	Species LD <sub>50</sub>		Dose D <sub>50</sub> /LC ATE <sub>n</sub>	<sub>50</sub> or 1	Exposure time	Results	
Oral:	-	rat	İ	LD <sub>50</sub>	)	-		mg/kg (ethanol) ng/kg (ethylene glycol)
Dermal:	-	rat		LD <sub>50</sub>	)	-		mg/kg (ethylene glycol) g/kg (phenol)
Inhalation:	-	rat	t	LC <sub>50</sub>	)	4 h	124.7 r	ng/l (ethanol)
Specific tar	get organ toxic	city – sir	ngle expos	ure (S	TOT SE):			
	Spe	ecific eff	fects			Target organ		Note
Oral:	No information	n availa	able	ole No ir		ormation available		-
Dermal:	No information	on availa	able	ble No in		nformation available		-
Inhalation:	on availa	ıble No inf			nformation available -			
!								
Aspiration I	nazard:		No	inforr	nation av	vailable.		
Irritation ar	d corrosion	4:	Consider	г.		NA - tla - al		Niete
Skin	Exposure	ume	Species in vitro	EV	aluation	Method		Note
corrosion/irritation:	-		study	_		OECD 431	cause	es burns (phenol)
Serious eye damage/irritation	-		rabbit	_		OECD 405	corro	sive (phenol)
Sensitizatio	n							
Skin sensitization:	No i	nformat	tion availal	ble.				
Respiratory sensitiza	tion: No i	nformat	tion availal	ble.				
					·			
Symptoms	related to the	physical	l, chemical	and t	oxicolog	ical characterist	ics	
Oral exposure:	No informa	ation av	ailable.					
Dermal exposure:	No informa	ation av	ailable.					
Inhalation exposure:	No informa	ation av	ailable.					
			ailable.					



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		Dose	Exposure time	Species	Method	Evaluation	n Note
Subacute oral	No ir availat	nformation ble	No information available	No information available	No information available	No information	on -
Subacute dermal	No ir availat	nformation ble	No information available	No information available	No information available	No informatio available	on -
Subacute inhalation	No information available		No information available	No information available	No information available	No informatio available	on -
Subchronic oral	No information available		No information available	No information available	No information available	No information available	on -
Subchronic dermal	No information available		No information available	No information available	No information available	No information available	on -
Subchronic inhalation	No information available		No information available	No information available	No information available	No informatio available	on -
Chronic oral	No ir availat	nformation ble	No information available	No information available	No information available	No informatio available	on -
Chronic dermal	No ir availat	nformation ble	No information available	No information available	No information available	No informatio available	on -
Chronic inhalation	No ir availat	nformation ole	No information available	No information available	No information available	No information	on -
Coosific	toract	raan tayisit	v repeated a	TOT2) enurs (STOT	DE).		
Specific	target c	ngan toxicit	y – repeated e Specific effec	xposure (STOT	Target o	rgan	Note
Subacute oral		No informa	tion available		No information		-
Subacute derma			tion available		No information		-
Subacute inhalat			tion available		No information		-
Subchronic oral		No informa	tion available		No information available		-
Subchronic derm	nal	No informa	tion available		No information	n available	-
Subchronic inhal	ation	No informa	tion available		No information	n available	_



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Chronic	oral	No information available		No information available	-			
Chronic	dermal	No information available		No information available	-			
Chronic	inhalation	No information available		No information available	-			
	CMR effects	(carcinogenicity; mutagenicity	y; reprod	ductive toxicity)				
	Carcinogenic	ity:	Based on available data, the classification criteria are not met.					
	Mutagenicity	ı in vitro:	Based o	on available data, the classification c	riteria are not met.			
	Genotoxicity	:	Based on available data, the classification criteria are not met.  Based on available data, the classification criteria are not met.  Based on available data, the classification criteria are not met.					
	Mutagenicity	ı in vivo:						
	Germ cell mu	utagenicity:						
	Reproductive	e toxicity:	Based on available data, the classification criteria are not met.					
	Summary coproperties:	of evaluation of the CM	CMR Based on available data, the classification criteria are not met.					
	<u>i</u>		<u>i</u>					
11.2	Information of	on other hazards:						
11.2.1.	Endocrine dis	srupting properties:						
	No known endocrine disrupting properties that affect human health.							
11.2.2.	Other inform	nations:						
	_							

SECTION 12. E	cological	information				
12.1 Toxicity	у					
Acute (short- term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	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 <sub>50</sub>	48 hours	Daphnia magna (Water flea)	-	-	7.800 mg/l (ethanol) >100 mg/l (ethylene glycol) 3.1 mg/l (phenol)



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Algae/aquatic plants	IC <sub>50</sub>	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 <sub>50</sub>	96 hours	No information available	<b>-</b>	-	-	
Crustacea:	EC <sub>50</sub>	18 hours	No information available	_	-	-	
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	_	-	-	
Other organisms	-	_	-	-	-	-	
	degrada						
	Degra	adation half-live	s Method	E	Evaluation	Note	
Marine water	No info	rmation availab	le No informatio	n No in availa	formation ble	-	
Fresh water	No info	rmation availab	le No informatio available	n No in availa	formation ble	-	
Air	No info	rmation availab	le No informatio available	n No in availa	formation ble	-	
Soil	No info	rmation availab	le No informatio available	n No in availa	formation ble	-	
ı							
Biodeg	radation			ī			
% Degradation	n	Time (days)	Method	Εν	valuation	Note	
94% (ethanol)	No ava	o informat ailable	OECD 301E	No in availa	formation ble	readily biodegradable	
85% (phenol)	14	days	OECD 301C	No in availa	formation ble	readily biodegradable	
12.3 Bioacc	umulativ.	notontial					
		potential partition coeffici	ont (log Kow)				
Octano	n-water β	artition Coeffici	ent (log Kow)	1			

°C

рΗ

Value

Concentration

Method

**Evaluation** 

Note



Trading name:

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_	-	-	-	-				-				ccumulation expected	is
	Bioconce	ntration 1	factor (BCF)										
V	alue	THE GET OF THE STATE OF THE STA	Species						/aluatio	uation Note			
No info availabl	information No inform		No information available		No information available		-						
	Chronic e	ecotovicit	W										
	Value	ecotoxicit	Dose		osure me	Spe	ecies	Meth	nod	Evalua	ation	Note	
Chronic toxicity on fish LC <sub>50</sub>		No information available			No ormation information			No information available		-			
	Chronic toxicity on crustacea ( <i>Daphnia</i> )		information in		No inforr availa	mation ible	No information available		No information available		-		
12.4	Mobility i	in soil											
	-		ed distributi	on in e	nvironme	ntal c	ompart	ments:					
	No inforr	nation av	ailable										
	Surface to	ension:											
	Value		°C	C	oncentrati	ion	*	Metho	od			Note	
	No informati available		ormation ailable	No information available		on No informatio available		n	-				
	Adsorption	on / deso	rption										
Transpo	ort	A/D coef Henry's co		lc	g Kow	Εν	/aporatio	on rate	N	1ethod		Note	
Soil-wa	ter No avai	in lable	formation	No ir availa	nformation able					No information available			
Water-a	air No avai	in lable	formation	No ir availa	nformation able		o inform ailable	ation	No in	formation ble	on -		



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Soil-air	No information available	No information available	No information available	No information available	-				
12.5	Results of PBT and vPvB asses	sment							
12.3	Based on available data, the product does not contain any PBT or vPvB substances.								
-	разова от втанавно васа, сто р								
12.6.	Endocrine disrupting properties								
	Based on available data, does not contain endocrine disruptors.								
12.7.	Other adverse effects								
	No further relevant information	on available.							
SECTIO	N 13. Disposal considerations	s							
13.1	Waste treatment methods								
	:								
13.1.1.	Product/Packaging disposal	:							
	Submit for disposal to the le	egal person autho	rized by the Ministi	y of Environmental	and Nature				
	Protection.								
13.1.2.	Waste codes/waste designa	tions according to	Law:						
	15 01 10*: Packaging that co			s or is contaminate	d with hazardous				
	substances								
13.1.3.	Waste treatment – relevant	information:							
	No information available								
13.1.4.	Sewage disposal – relevant	information:							
13.1.7.	Waste must not be disposed		ne system						
	waste mast not be disposed		qc bystein.						
		a of file the sewa	<u> </u>						
13.1.5.	Other disposal recommenda		<i>.</i>						
13.1.5.	Other disposal recommendate  Do not dispose of the product authorized by the ministry in the packaging to the collect	ations: uct's remains into n charge. Do not o	the sewage system	aging into the sewa					
13.1.5.	Do not dispose of the produ	ations: uct's remains into n charge. Do not c cors authorized by	the sewage system	aging into the sewa					
	Do not dispose of the produ authorized by the ministry in the packaging to the collect	ations: uct's remains into n charge. Do not o ors authorized by ions:	the sewage system dispose of the pack the ministry in cha	aging into the sewa					



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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:	III
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:	Ш
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:	Ш
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (II	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:	Ш
Environmentally hazardous:	-



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Special precautions for user:	-
Further information: -	

SECTION	ON 15. Regulatory informa	ation				
15.1	Safety, health and environ	nmental regulations/legislation specific for the substance or mixture				
	EU regulations					
	Authorization and/or rest	rictions of use				
	Authorizations:	-				
	Restrictions:	-				
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 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; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);				
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-				
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act				
15.2	Chemical safety assessme	ent				
	None					

SECTION 16. Other information	
16.1 Indication of changes:	



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16.2	Abk	previations and acrony	yms:	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.		literature references rce of data:	and	-		
16.4.	4. Classification and procedure us 1272/2008 (CLP)			ed to derive the classification for mixture according to Regulation (EC)		
Classifi	Classification C		C	assification procedure		
-			-			
16.5.	Relevant H statements (number and full text)					
		H225	Highl	y flammable liquid and vapor.		
		H226	Flamı	mable liquid and vapor.		
		H301	Toxic	ic if swallowed.		
	H:	H302	Harm	ful if swallowed.		
		H311	Toxic	ric in contact with skin.		
		H314	Cause	es severe skin burns and eye damage.		
		H331	Toxic	if inhaled.		
		H341	Suspe	ected of causing genetic defects.		
		H373	May	cause damage to organs through prolonged or repeated exposure.		
16.6.	Trai	ning advice:	-			
16.7.	** "X" in the product code marks different volumes (different packagings of product)  We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		uct) re not responsible for consequences in case of failure to comply with actions for use or improper use of the product described in this material			

ANNEX: Exposure scenario resulting to chemical safety assessment	
-	



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

amended by Regulation (EU) No. 2020/878

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

SECTI	ON 1: Identification of	the substance	e/mixture	and of the company/undertaking	
1.1	Product identifier				
	Trading name:	TB DECOLO	RIZER		
	Chemical name:	-			
	Catalogue number:	TBD-OT-X*	TBD-OT-X**		
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 sheet				
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent p	erson:	msds@biognost.hr		
	National contact:		-		
1.4	Emergency telephone number				
	National Protection ar	nd Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

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



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

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

SECTION 3. Co	SECTION 3. Composition/information on ingredients					
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)		
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- 0147	70 - 90 %	ethanol	Flam. Liq. 2; H225		
7647-01-0/ 231-595-7/ 017-002-00-2	-	2 -3 %	hydrochloric acid, 37%	Skin Corr. 1B; H314 STOT SE 3; H335		

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



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

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



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

5.4	Additional information
	-

	ON 6. Accidental release measu			
6.1	Personal precautions, protective equipment and emergency procedures			
6.1.1.	For non-emergency personnel			
	Protective equipment:	Use personal protective equipment (see Section 8).		
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.		
	Emergency procedures:	Mark the area using proper signs.		
6.1.2.	For emergency responders:			
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.			
6.2	Environmental precautions:			
	Dispose of the spillage and the resulting waste according to the applicable environmental regular not allow the product and the resulting waste to enter sewers/soil/surface or ground water. It respective authorities in accordance with local law in the case of environmental pollution immediately.			
6.3	Methods and material for conta	ainment and cleaning up		
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.		
6.3.2.	Cleaning up:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).		
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).		
6.4	Reference to other sections			
	See Section 7 for information o	n safe handling.		
	See Section 8 for information on personal protection equipment.			
	See Section 6 for information 6	become become education		

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



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	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use non-sparkling tools and equipment.		
	Measures to prevent aerosol and dust generatio	n:	Ensure adequate ventilation.	
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.	
	Other measures:		Protect against electrostatic charges.	
7.1.2.	Advice on general occupational hygiene:			
	Do not eat, drink or smoke in the workspace. The	oroughly wa	sh hands after work and before eating.	
7.2	Conditions for safe storage, including any incom	patibilities		
	Technical measures and storage conditions:	Store in a well-ventilated place, protected from sunl away from sources of heat and ignition, in its origunopened and hermetically sealed packaging, a from oxidizing agents, food, feed and articles consumption.		
	Packaging materials:	Manufactı	urer's original packaging.	
	Requirements for storage rooms and vessels:	Keep away tightly clo	y from food and drink. Keep the containers sed.	
	Advices for storage equipment:	be resista	ge must be made of hard material; floors must nt to chemicals. There must be no drain that eads into sewage system. Secure proper n.	
	Further information on storage conditions:	Do not place the unused material in the storage roc and do not use empty containers for storing oth chemicals. Do not store with incompatible materials (s Section 10).		
7.3	Specific end use(s)			
	Recommendations:	-		
	Industrial sector specific solutions:	_		

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



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



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	Structural measures to prevent exposure:		In accordance with Section 7.		
	Organisational measures to preve exposure:	nt	Organization of work in order to reduce other worker's influence during work process.		
av co		oosure:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation.		
			Use non-sparkling ventilation system.		
			Provide appropriate personal protective equipment, safety shower and eye-wash station.		
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield (EN ISO 16321-1:2022, EN 166).			
8.2.2.2.	Skin protection				
	Hand protection:	Use ap	propriate, chemical-resistant protective gloves (EN 374).		
	Other skin protection:	Use 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 stration of ethyl alcohol exceeds occupational exposure limits air, use a self-contained breathing apparatus. For short and if the oxygen content of the air is greater than 18 %, use ective gas mask with filter A (EN 14837/A1).		
8.2.2.4.	Thermal hazards:	No the	rmal hazards known.		
8.2.3.	Environmental exposure controls				
	Substance/mixture related measures to prevent exposure:	See Se	ction 6		
	Structural measures to prevent exposure:	Use mo	odern equipment.		
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.		
	Technical measures to prevent exposure:	See Se	ction 6		

SECT	SECTION 9. Physical and chemical properties					
9.1	.1 Information on basic physical and chemical properties					
		Value	Method			
	Physical state:	liquid	No information available			
	Colour:	colourless	No information available			



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

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

SECTION	SECTION 11. Toxicological information				
11.1	1.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				



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

Product code:	TBD-OT-X*	* Revi	sion date:	21 Dec	2022	V	/ersion: 5
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /		Exposure tir	me	Results
Oral:	_	rat (ethanol)	LD <sub>50</sub>		_		7.060 mg/kg
Dermal:	-	rabbit (ethanol)	LD <sub>50</sub>		_		>20.000 mg/l
Inhalation:	_	rat (ethanol)	LC <sub>50</sub>		4 h		>8.000 mg/l
Specific ta	rget organ to	xicity – single expos	ure (STOT SE):				
3 7	S	pecific effects		Target org	an		Note
Oral:	No informa	tion available	No info	rmation ava	ilable	-	
Dermal:	No informa	tion available	No info	rmation ava	ilable	-	
Inhalation:	No informa	tion available	No info	rmation ava	ilable	-	
Aspiration	hazard:	No	information a	vailable.			
Irritation a	nd corrosion						
	Ехро	osure time	Species	Evaluation	Method		Note
Skin corrosion/irritation:	-	-		-	-	-	
Serious eye damage/irritation	-	-		-	-	-	
Sensitizatio	on						
Skin sensitization:		information availab	ole.				
Respiratory sensitiz		information availab					
	<u> </u>						
Symptoms	related to the	e physical, chemical	and toxicolog	ical characte	eristics		
		on of great qua	•				•
Oral exposure:		ousness and alcohol may occur. Repeate			5 5	•	
Dermal exposure:		After prolonged or repeated exposure symptoms may include: defatting, d cracking of skin.					ing, dryness an
Inhalation exposure	Inhalation membrar	n of great quantities nes.	may cause diz	ziness, euph	oria and mild	lirritat	ion of the mucoι
_							

Repeated dose toxicity (subacute, subchronic, chronic)

May cause irritation and redness.

Eye exposure:



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Trading name:	TB DECOLORIZER					
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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	_
Subacute dermal	No information available	No information available	No information available	No information available	No information available	<b>-</b>
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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



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

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



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Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

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

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

12.3	Bioacc	accumulative potential							
	Octano	Octanol-water partition coefficient (log Kow)							
Value Concentration pH °C Method				Evaluation	Note				
Log Pov 0.32	W: ~	-	-	-	-	-	The product does not bioaccumulate		



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rioduc	it code.		7-01-X					-			
	Riocons	antratio	on factor (BCF)								
		=1111 ati0			<b>k</b> /	loth od		F = 1	luatio :-	**	Note
V	/alue		Species			lethod 			luation 		Note
BCF: 0.6	56	No avai	o information ailable		No info			No infor		-	
	Chronic	ecotoxi	city								
	Value		Dose	1	osure me	Specie	es	Metho	d	Evaluation	Note
Chronic toxicity on fish LC <sub>50</sub>		No infori availa	mation able	No informat available		No informat available	1	o formation ailable	-		
Chronic toxicity on crustacea ( <i>Daphnia</i> )		EC <sub>50</sub>	No infori availa	mation able	No informat available		No informat available		o formation vailable	-	
12.4		or predi	cted distributi available	on in e	environme	ental com	npartr	ments:			
	Surface	tension	•								
	Value	e	°C	C	oncentrat	ion		Method			Note
	No informat		No	No							
	available		information available		informat ilable		o info vailab	ormation le		-	
	available									-	
		2 (								-	
Transpo	Adsorpti	ion / de	available	ava		a	vailab		Met	thod	Note
Transpo Soil-wa	Adsorpti	ion / de	esorption coefficient y's constant information	lo	og Kow oformatio	Evap	oratic	on rate ation	Met No infor available	thod	Note -
	Adsorpti	ion / de A/D Henry	esorption coefficient y's constant information ole information	lo No ir availa	og Kow oformationable	Evap n No ir	oratic oformable	on rate ation	No infor	thod mation	Note -



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12.5	Results of PBT and vPvB assessment
	Based on available data, the product does not contain any PBT or vPvB substances.
12.6.	Endocrine disrupting properties
	Based on available data, does not contain endocrine disruptors.
12.7.	Other adverse effects
	Do not let the product or its residues reach sewer system, waterways and soil.
SECTIO	N 13. Disposal considerations
13.1	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature
	Protection.
13.1.2.	Waste codes/waste designations according to Law:
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors
	authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Unused product residues may be
	burnt.
13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.
SECTIO	N 14 TRANSPORT INFORMATION
	Transporting/shipment by road (ADR)
UN num	
	per shipping name: Ethanol solution
2 p.or	



Environmentally hazardous:

Special precautions for user:

Further information:

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

-



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15.1	Safety, health and enviror	nmental regulations/legislation specific for the substance or mixture
	EU regulations	
	Authorization and/or rest	rictions of use
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
		REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessme	ent
	None	

SECTION 16. Other information	
16.1 Indication of changes:	-



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16.2	Abbrevi	ations 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 lite	rature references and of data:	-		
16.4.		cation and procedure 008 (CLP)	used to derive the classification for mixture according to Regulation (EC)		
Classif	ication		Classification procedure		
_			-		
16.5.	Relevan	it H statements (numb	per and full text)		
	H:	225	Highly flammable liquid and vapour.		
		314	Causes severe skin burns and eye damage.		
		335	May cause respiratory irritation.		
16.6.	Training	g advice:	-		
16.7.	Further information:		** "X" in the product code marks different volumes (different packagings of the product)  We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

ANNEX: Exposure scenario resulting to chemical safety assessment	
-	



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

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Trading name:	TB MALACHITE GREEN REAGENT		
Product code:	TBM-OT-X**	Date of compilation: 14 November 2022	Version: 4

SECTI	ON 1: Identification of	the substar	nce/mixture	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	TB MALA	TB MALACHITE GREEN REAGENT		
	Chemical name:	-			
	Catalogue number:	TBM-OT-X**			
1.2.	Relevant identified us	es of the sul	bstance or mi	xture and uses advised against	
	Uses:		For use in	TB-Stain Cold kit.	
	Uses advised against:		Only the i	dentified 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	Details of the supplier of the safety data sheet			
	Supplier: B		BioGnost Ltd	3ioGnost Ltd.	
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Fax no.:		+385 1 2404039		
	e-mail of competent p	e-mail of competent person:		msds@biognost.hr	
	National contact:		-		
1.4.	Emergency telephone	Emergency telephone number			
	National Protection a	National Protection and Rescue Dire		112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards identification				
2.1.	Classification of the substance or mixture				
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)				
	Hazard class and categor	y code:	Hazard statements*:		
	Not identified as hazardous subs	stance.	-		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazard-st	tatements: see S	ection 16		
2.2.	Label elements				
	Product identification:	TB MALACHI	TE GREEN REAGENT		
	Identification number:	-			
	Authorization no.:	-			
	Hazard pictograms:	-			



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Trading name:	TB MALACHITE GREEN REAGENT			
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	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	Endocrine Disrupting Properties:	
	No known endocrine disrupting prop	erties.

SECTION 3. Composition/information on ingredients					
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)	
2437-29-8/ 219-441-7/ 602-096-00-5	-	< 0.25%	bis[[4-[4- (dimethylamino)benzhydrylide ne] cyclohexa-2,5-dien-1- ylidene]dimethylammonium] oxalate, dioxalate	Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410	

4.1.	Description of first aid measures		
	General notes:	-	
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.	
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.	
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.	
	Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.	
	Self-protection of the first aid	er: Treat symptomatically.	
4.2.	Most important symptoms an	d effects, both acute and delayed	
	Following inhalation.	Allergic persons may display irritation after prolonged or repeated exposure.	



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	Following skin contact:	Allergic persons may display irritation.
	Following eye contact:	May cause irritation.
	Following ingestion:	Swallowing may cause discomfort in abdomen and abdominal pains.
4.3.	Indication of any immedia	te medical attention and special treatment needed
	-	

SECTI	ECTION 5. Firefighting measures			
5.1.	Extinguishing media			
	Suitable extinguishing media:  Small fire - water spray, dry powder, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam			
	Unsuitable extinguishing media: water jet			
5.2.	Special hazards arising from the substance or mixture			
	Hazardous combustion products: No information available			
5.3.	Advice for firefighters			
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.  Cool closed containers exposed to fire with water spray or vapor.			
5.4.	Additional information			
	Remove sources of heat and ignition.  Do not contaminate the environment with extinguishing media.			

SECTIO	SECTION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personne				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods:  Evacuate members of all non-essential personnel and the members without protective equipment. Remove all sources sparks and ignition. Do not smoke.				
	Emergency procedures: Mark the area using proper signs.				
6.1.2.	For emergency responders:				
	Wear protective equipment (see Section 8).				
6.2.	Environmental precautions:				
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.				
6.3.	Methods and material for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.			



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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). 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:	-
6.4.	Reference to other section	ns
	See Section 8 for informa	ation about secure handling. ation about personal protective equipment. nation about containment.

SECTIO	ON 7. Handling and storage				
7.1.	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:		Keep away from sources of heat and ignition. Do not smoke.		
	Measures to prevent aerosol and dust go	eneration:	Secure proper ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:		-		
7.1.2.	Advice on general occupational hygiene	:			
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.				
7.2.	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:	ventilate	tightly closed and upright set containers in a well ed storage rooms, and away from sources of heat, , and other incompatible substances.		
	Packaging materials:	Manufa	cturer's original packaging.		
	Requirements for storage rooms and vessels:	Keep av closed.	vay from food and drink. Keep the containers tightly		
	Advices for storage equipment:	resistan	rage must be made of hard material; floors must be to chemicals. There must be no drain that directly to sewage system. Secure proper ventilation.		
	Further information on storage conditions:	not use	place the unused material in the storage room and do empty containers for storing other chemicals. Do not th incompatible materials (see Section 9).		
7.3.	Specific end use(s)				
	Recommendations:	-			



Air

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Trading name:			<b>.</b>	ΓΒ MALACHIT	TE GREEN REA	AGENT			
Product code:	TBM-O	T-X**	Date	of compilation	n: 14 Novem	nber 2022	Version: 4		
Industrial s	ector spe	cific solutio	ns:	-					
CECTION O. Farrage		-1-1	.1	4					
8.1. Control pa		ois/persona	ai protec	tion					
o. i. Control pa	rameters			Occupational	exposure limit				
Substance		CAS I	No		t term values	Biolo	gical limit values		
Substance			ppm	mg/m³	]	gicai iiiiic valaes			
-		-		-	-	No informa	ation available		
		•		•	1	-			
Substance _									
name: -		CAS No:							
DNEL -		CAS INO.							
DNEL				Industrial					
	<u> </u>	Acute		Acute	Chror	nic	Chronic		
Route of exposure:		ect local	effe	ect systemic	effect l		effect systemic		
Oral	-		-	<u> </u>	-	-	·		
Inhalation	-		-		-	-			
Dermal	-		-		-	-			
Critical physical par	ameters:	solubility, fla	mmabili	ty, corrosivity:	-				
				Consumer	·				
Route of exposure:	,	Acute		Acute	Chror	nic	Chronic		
Route of exposure.	effe	ect local	effe	ect systemic	effect l	ocal	effect systemic		
Oral	-		-		-	-			
Inhalation	-		-		-				
Dermal	-		-		-	-			
PNEC									
Environmental prot	ection tar	get		PNEC					
Fresh water					mation availab				
Freshwater sedimer	nts				mation availab				
Marine water					mation availab				
Marine sediments					mation availab				
Food chain					mation availab				
Microorganisms in	sewage tr	eatment			mation availab				
Soil (agricultural)				No infor	No information available				

No information available No information available



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Trading name:		TB MALACHITE	GREEN REAGENT	
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8.2.	Exposure controls					
8.2.1.	Appropriate engineering controls					
	Substance/mixture related measures to prevent exposure during identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to perfect exposure:	revent	No information available			
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prexposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equi	ipment				
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing visor.				
8.2.2.2.	Skin protection					
	Hand protection:		ctive gloves must be according to the EU Directive 2016/425/EEC and ard EN 374.  Glove material: nitrile rubber  Glove thickness: ≥0.50 mm  Break through time: >480 min			
	Other skin protection:		Vear antistatic clothing made of natural fibers (such as cotton) with long leeves (EN 13034), and shoes that cover the entire foot (EN 10335).			
8.2.2.3.	Respiratory protection:	filter f	ctive full face mask (EN 136) or half mask (EN 140) equipped with a for organic vapors, type "A" (boiling point >65°C) acording to EN () used when concentration levels exceed GVI.			
8.2.2.4.	Thermal hazards:	No in	formation available			
8.2.3.	Environmental exposure	controls				
	Substance/mixture relate measures to prevent exp		See Section 6			
	Structural measures to perfect exposure:	revent	Use modern equipment.			
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.			
	Technical measures to prexposure:	event	See Section 6			

#### **SECTION 9. Physical and chemical properties**

9.1. Information on basic physical and chemical properties



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Trading name:		TB MALACHITE GREEN REAGENT	-
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	Value	Method
Physical state:	liquid	No information available
Color:	blue-green	No information available
Odour/odour threshold:	no odor/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
Flash point:	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
рН:	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
Other information		

SECTIO	ON 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.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
10.6.	Hazardous decomposition products:	No information available.

#### **SECTION 11. Toxicological information**

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



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Acute toxici	ty:					
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure t	ime	Results
Oral exposure:	No information available	-	LD <sub>50</sub>	-		-
Dermal exposure:	No information available	-	LD <sub>50</sub>	-		<del>-</del>
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-		-
Specific targ	get organ toxicity – sir	ngle exposure (S	STOT SE):			
	Specifi	c effects	Targe	t organ		Note
Oral exposure:	No information a	vailable	No informati	on available	-	
Dermal exposure:	No information a	vailable	No informati	on available	-	
Inhalation exposure:	No information a			on available	-	
ппаанен ехрозате.				on available		
Aspiration h			mation available			
Aspiration h	nazard: d corrosion:	No infor	mation available			
Aspiration h	d corrosion:  Exposure time	No infor		Method		Note
Aspiration has Irritation an Skin irritation:	d corrosion:  Exposure time	No infor Species rabbit	mation available  Evaluation	Method 		Note
Aspiration h	d corrosion:  Exposure time	No infor	mation available	Method		Note
Aspiration has Irritation an Skin irritation:	d corrosion:  Exposure time -	No infor Species rabbit	mation available  Evaluation	Method 		Note
Aspiration has Irritation an Skin irritation: Eye irritation:	d corrosion:  Exposure time -	Species rabbit rabbit	mation available  Evaluation	Method 		Note
Aspiration has Irritation an Skin irritation: Eye irritation: Sensitization	d corrosion:  Exposure time  -  -	Species rabbit rabbit	mation available  Evaluation	Method 		Note
Aspiration has Irritation and Skin irritation: Eye irritation: Sensitization Dermal exposure: Inhalation exposure:	d corrosion:  Exposure time  -  -  No information availa	Species rabbit rabbit	Evaluation	Method 		Note
Aspiration has Irritation and Skin irritation:  Eye irritation:  Sensitization:  Dermal exposure: Inhalation exposure:  Symptoms in the specific property of the specific p	d corrosion:  Exposure time  -  -  No information availation	Species rabbit rabbit able able	Evaluation toxicological chara	Method		Note
Aspiration has Irritation and Skin irritation:  Eye irritation:  Sensitization:  Dermal exposure: Inhalation exposure:  Symptoms in Oral exposure:	nazard:  d corrosion:  Exposure time  No information availa  No information availa	Species rabbit rabbit able able l, chemical and ause discomfort	Evaluation toxicological chara	Method		Note
Aspiration has Irritation and Skin irritation: Eye irritation: Sensitization Dermal exposure: Inhalation exposure:	nazard:  d corrosion:  Exposure time  -  -  No information availa  No information availa  related to the physica  Swallowing may ca  Allergic persons m	Species rabbit rabbit able discomfort ay display irrita	Evaluation toxicological chara in abdomen and tion.	Method acteristics abdominal pair	ns.	



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

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



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Chronic	inhalation	No informa	tion available	No information available	-	
	CMR effects (c	carcinogenicity	r; mutagenicity; repr	oductive toxicity)		
	Carcinogenicit	ty:	Current studies	on test animals did not indicate o	arcinogenic effects.	
	Mutagenicity	in-vitro:	Current <i>in vitr</i>	o tests did not indicate mutager	nic effects.	
	Genotoxicity:		No information	ı available		
	Mutagenicity <i>in-vivo</i> : Current <i>in vivo</i> tests did not indicate mutagenic effects.				ic effects.	
	Germ cell mut	agenicity:	No information available			
	Reproductive	toxicity:	No toxicity on reproductive organs was determined in reproductivorgans.			
	Summary of e	valuation of th	ne CMR properties:	-		
11.2.	Information on other hazards:					
11.2.1.	Endocrine disrupting properties:					
	No known end	No known endocrine disrupting properties that affect human health.				
11.2.2.	Other informa	itions:				
	-					

SECTION 12. Ecological information						
12.1. Toxicity						
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	-	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC <sub>50</sub>	8 days	No information available	No information available	_	_
Microorganisms	LC <sub>50</sub>	72 hours	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-



Trading name:

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

**TB MALACHITE GREEN REAGENT** 

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Produc	ct code:	TBM-OT-	X**	Date o	f compilation:	14	4 November	r 2022	Ve	rsion:	4
Algae/a	aquatic pla	ants IC <sub>50</sub>	72 hours		o information vailable		information ilable	No inforn availa	nation ble	-	
Other o	organisms	-	-	-		_		_		-	
12.2.		nce and degra	dability								
	Abiotic (	degradation	half lives		Mathad		г.	, alvatia			Note
Marine		Degradation			Method		EV	/aluatio	)rı		Note
water	N	lo informatior	available	No in	formation availa	able	No informa	tion ava	ailable	-	
Fresh w	ater N	lo informatior	ı available	No in	formation availa	able	No informa	tion ava	ailable	-	
Air	N	lo informatior	ı available	No in	formation availa	able	No informa	tion ava	ailable	-	
Soil	N	lo informatior	available	No in	formation availa	able	No informa	tion ava	ailable	-	
	ı										
	Biodegra										
	radation	Time (d		Method			Evaluation		Note		
No info availabl	No information No information vailable available							No infor available			
						•		•			
12.3.	Bioaccui	mulative pote	ntial								
	Octanol-	-water partitic	n coefficien	t (log Ko	ow)						
Valu	e C	Concentration	рН	°C	°C Method		Evaluation			Note	ı
-	No ava	informatio ailable	n -	-	No information available	on	No informa available	tion	-		
	ъ.		(DCT)								
		entration facto			Mother d		Fugl			Nata	
	'alue	No Sp	ecies information	n Nai	Method	NI.	Evaluation o information		No info	Note	
No information available		available	iniormatio				vailable	1	availabl		1
availabl											
availabl											
availabl											
availabl		ecotoxicity									



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	Va	llue	Dose	Exposure time	Sp	ecies	Method	Evaluati	on Note
Chroni	c toxid	city on fish	LC <sub>50</sub>	No information available	No infor avail	1	ormation ailable	No informatio available	n -
Chroni crustac		city on aphnia)	EC <sub>50</sub>	No information available	No infor avail		ormation ailable	No informatio available	n -
12.4.	Mol	bility in soi	il						
		-	dicted distributi	on in environ	mental	compartmer	nts:		
	No	informatio	n available						
	Surf	face tensio	n:			_			
	,	Value	°C	Concent	ration	M	ethod		Note
		rmation ilable	No information available	No inform available	ation	No inform available	information lable		
			<u>.</u>	i					
Transp	1	A/D	desorption coefficient 's constant	log Kow	Eva	poration rate	e Me	ethod	Note
Transp Soil-wa	ort	A/D	coefficient 's constant information	log Kow  No informatio n available		ormation		ormation	Note -
	ater	A/D d Henry	coefficient 's constant information information	No informatio	No inf	ormation ble ormation	No info	ormation le ormation	
Soil-wa	ort ater	A/D of Henry No available	coefficient /'s constant information information information	No informatio n available No informatio	No inf availab No inf availab	ormation ole ormation ole ormation	No info availab No info availab	ormation le ormation le ormation	
Soil-wa	ort ater -air	A/D of Henry No available No available No available	coefficient /'s constant information information information	No informatio n available No informatio n available No informatio n available	No inf availab No inf availab	ormation ole ormation ole ormation	No info availab No info availab	ormation le ormation le ormation	
Soil-wa Water- Soil-air	ater -air	A/D of Henry No available No available No available ults of PBT	information  information  information	No informatio n available No informatio n available No informatio n available	No inf availab No inf availab	ormation ole ormation ole ormation	No info availab No info availab	ormation le ormation le ormation	
Soil-wa	ater -air	A/D of Henry No available No available No available ults of PBT	coefficient /'s constant information information information	No informatio n available No informatio n available No informatio n available	No inf availab No inf availab	ormation ole ormation ole ormation	No info availab No info availab	ormation le ormation le ormation	
Soil-wa	ater -air Res No	A/D of Henry No available No available No available ults of PBT	information  information  information	No informatio n available No informatio n available No informatio n available ssment	No inf availab No inf availab	ormation ole ormation ole ormation	No info availab No info availab	ormation le ormation le ormation	



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12.7.	Other adverse effects					
	No adverse effects are expected.					
SECTION	SECTION 13. Disposal considerations					
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
	Submit for disposal to the legal Protection.	l person authorized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste designation	ns according to Law:				
	No information available					
13.1.3.	Waste treatment – relevant info	ormation:				
	No information available					
13.1.4.	Sewage disposal – relevant info	ormation:				
	Waste must not be disposed of	f into the sewage system.				
13.1.5.	Other disposal recommendatio	ns:				
	authorized by the ministry in ch	s remains into the sewage system. Submit the remains to the collectors narge. Do not dispose of the packaging into the sewage system. Submit authorized by the ministry in charge. Do not dispose of in places where				
13.1.6.	Relevant Community provisions	s:				
	-					
SECTION	l 14. Transport information					
	Transporting/shipment by road (A	ADR)				
UN numl	ber:	Not subject to transport regulations.				
UN prop	er shipping name:	-				
Transpor	t hazard class(es):	-				
Packing o	group:	-				
Environm	nentally hazardous:	-				
Special p	recautions for user:	-				
	Transporting/shipment by rail (RID)					



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UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (II	MDG)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information: The product is	not subject to classification.

SECTIO	SECTION 15. Regulatory information				
15.1.	Safety, health and enviro	Safety, health and environmental regulations/legislation specific for the substance or mixture			
	EU regulations				
	Authorization and/or restrictions of use				
	Authorizations:	-			



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	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; 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	

dication of changes:				
<u> </u>	-			
	PBT	Stable, bioaccumulative and toxic Strongly stable and strongly bioaccumulative.		
bbreviations and acronyms:	LD <sub>50</sub>	Lethal dose, 50%		
	LC <sub>50</sub>	Lethal concentration, 50%		
	STOT-SE	Specific target organ toxicity - single exposure		
ey literature references and ource of data:	-			
Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
Classification Classification procedure		cedure		
-		-		
16.5. Relevant H statements (number and full text)				
2	ey literature references and ource of data: assification and procedure use 272/2008 (CLP) on C	vPvB  LD <sub>50</sub> LC <sub>50</sub> STOT-SE  ey literature references and aurce of data:  assification and procedure used to derive the extraction procedure used to derive the control of the control o		



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	H:   -	-
16.6.	Training advice:	-
		** "X" in the product code marks different volumes (different packagings of the product)
16.7.	Further information:	We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessme	nt
-	