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Trading name:	METHYLENE GREEN, C.I. 52020					
Product code:	MEG-P-X**	Revision date:	21 Dec 2022	Version:	3	

SECTI	ON 1 Identification of the subs	tance	/mixture an	d of the company/undertaking	
1.1.	Product identifier				
	Substance name:	METH	HYLENE GREE	EN, C.I. 52020	
	EC No:	-	-		
	Synonyms:	Meth	Methylene Green		
	Product code:	MEG	-P-X**		
	REACH registration number:	-			
	CAS No:	2249	67-52-6		
	Index no.:	-			
1.2.	Relevant identified uses of the	e substance or mixture and uses advised against			
	Uses:		nuclei green.		
	Uses advised against:	Only the identified uses are advised.		entified uses are advised.	
	Reason why uses advised aga	The product is intended for use only as an <i>in vitro</i> diagnostic medical device listed in the Registry of medical devices at the Agency for Medicinal Products and Medical Devices and there reason to use it for other purposes			
1.3.	Details of the supplier of the s	afety	data sheet		
	Supplier:	Bi	oGnost Ltd.		
	Address:	М	edjugorska 5	9, Zagreb	
	Telephone number:	+3	385 1 240999	97	
	Fax no.:	+3	385 1 240403	39	
	e-mail of competent person:	<u>m</u>	sds@biogno	<u>st.hr</u>	
	National contact person:	-			
1.4.	Emergency telephone numbe	r			
	National Protection and Rescu	ıe Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ION 2. Hazards identification					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)					
	Hazard class and category code: Hazard statements*:					
	Not identified as hazardous substances -					
2.1.2.	Additional information					
	-					
*For fu	II text of Hazard- and EU Hazard-statements: see	Section 16				



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2.2.	Label elements				
	Product identification:	METHYLENE GREEN, C.I. 52020			
	Identification number:	-			
	Authorisation number:	-			
	Hazard pictograms:	-			
	Signal word:	-			
	Hazard statements:	-			
	Precautionary statements:	-			
	Further information:	-			
2.3.	Other hazards				
	Endocrine Disrupting Propert	ies:			
	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 No	EC No:	Index no.	Identification name	Weight % content (or range)		
224967-52-6	-	-	3,7-bis(dimethylamino)-4- nitrophenothiazin-5-ium chloride	90-100 %		

SECTIO	CTION 4. First aid measures				
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 begin rinsing with copious amounts of water for at least 15 min. 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. If the afflicted person is unconscious, do not provide them with anything orally. Drink at most two glasses of water. Seek medical assistance.			
	Self-protection of the first aider	-			
4.2.	Most important symptoms and effects, both acute and delayed				
	Following inhalation:	Harmful if inhaled.			



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	After skin contact:	Harmful in contact with skin.
	Following eye contact:	Risk of serious damage to eyes.
	Following ingestion:	Harmful if swallowed.
4.3.	Indication of any immediate	medical attention and special treatment needed
	-	

SECTIO	ECTION 5. Firefighting measures				
5.1.	Extinguishing media				
	Suitable extinguishing media: Water, foam, dry powder, CO ₂				
	Unsuitable extinguishing media: -				
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				
	Make sure the water used for extinguishing fire does not contaminate water surface or underground waters system.				

SECTIO	ECTION 6. Accidental release measures					
6.1.	Personal precautions, protective equipment and emergency procedures					
6.1.1.	For non-emergency p	For non-emergency personnel				
	Protective equipment:		Use personal protective equipment (see Section 8).			
	Accident prevention n	nethods:	Avoid breathing in dust. Avoid touching the substance. Secure proper ventilation.			
	Emergency procedure	s:	Leave the hazardous area, take notice of the emergency procedures.			
6.1.2.	For emergency responders:					
	-					
6.2.	Environmental precau	tions:				
	Do not allow the prod	uct enter dra	ainage.			
6.3.	Methods and material	for preventi	ing spreading and cleaning			
6.3.1.	For creating barriers, cover the drains. Collect, bind and pump out all the spilled material. Take notice of the possible material restriction (see Sections 7 and 10). Collect in dry form. Avoid generation of dust.					
6.3.2.	Cleaning up:	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				



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		materials with water.		
6.3.3.	Other information:	-		
6.4.	Reference to other sec	ctions		
	Indications about waste treatment, see Section 13.			

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 ignition and heat. Do not use sparkling tools.	
	Measures to prevent aerosol and dust generati	on: Secure proper ventilation.	
	Environmental precautions:	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:	Minimize dust formation. Avoid breathing in dust. Avoid contact with skin, eyes, and clothes. Keep in tightly closed containers.	
	Containers materials:	Manufacturer's original packaging.	
	Requirements for storage rooms and vessels:	Keep in a tightly closed container. Keep in cool, dry and well ventilated space away from non-compatible substances.	
	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:	No information available.	
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				



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Trading r	name:	me: ME				THYLENE GREEN, C.I. 52020				
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		•				,	,			
-			-		-		-		-	
Does not	contain s	ubstances re	gulated by	the professio	nal exp	posur	e limit values.			
Substance name:	-									
EC No:	-		CAS No:	-						
DNEL	·			i						
				Ind	lustrial	I				
Route of exposure	•		cute t local	Acut			Chronic effect local		Chroni effect syst	
Oral		-	t local	-	Sterrife		-		-	CITIC
Inhalation		-		_			_		_	
Dermal		-		-			_		_	
	vsical pa	rameters: so	ubility flam	ı nmability, corı	osivity	<i>j</i> .				
Circical pri	ysicai pai		ability, nam	· · · · · · · · · · · · · · · · · · ·	nsume					
Route of		Ac	cute	Acut			Chronic		Chronic	
exposure	:		t local	effect systemic			effect local		effect systemic	
Oral		-		-			-		-	
Inhalation		-		-			-		-	
Dermal		-		-			-		-	
PNEC										
Environme	ental pro	tection targe	t		PNE	C				
Fresh wate	er				No ii	nforn	nation available			
Freshwate	r sedime	nts			No information available					
Marine wa	ater				No information available					
Marine se	diments				No information available					
Food chai	n				No ir	nforn	nation available			
Microorga	nisms in	sewage trea	tment		No information available					
Soil (agric	ultural)				No ii	nforn	nation available			
Air					No ii	nforn	nation available			
8.2.	Exposur	e controls								
8.2.1.	Approp	riate enginee	ering contro	ols	Ţ					
	Substance/mixture related measures to prevene exposure during identified uses:			Use personal protective equipment. Do not eat, drin or smoke in the workspace.				at, drink		
	Structur	al measures	to prevent	exposure:	N	lo inf	ormation availab	ole		
	Organis	ational meas	ures to pre	vent exposure	e: O	Crganization of work in order to reduce other				



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			worker's influence during work process.			
	Technical measures for prevention	ng exposure	Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.			
8.2.2.	Personal protection equipment					
8.2.2.1.	Eye and face protection:	Safety gla 166).	sses that stick to face (preventing splashing) or visor (EN			
8.2.2.2.	Skin protection					
	Hand protection:		Gloves material: Nitrile rubber Glove thickness: 0.11 mm Break through time:> 480 min			
	Other skin protection: such as r spillage i protectio		circumstances use cotton clothes and adequate footwear, bber boots or shoes that cover the entire foot. In case of sk use clothes made of impermeable material suitable for against liquid chemicals (Viton, PVC himex - HRN EN 465) tear made of the same material.			
8.2.2.3.	Respiratory protection:		when dust are generated. Recommended filter type: Filter P DIN 3181) for solid and liquid particles of toxic and very tances.			
8.2.2.4.	Thermal hazards:	-				
8.2.3.	Environmental exposure control	S				
	Substance/mixture related meas prevent exposure:	sures to	See Section 6			
	Structural measures to prevent e	exposure:	Use modern equipment.			
	Organisational measures to prevent exposure:		Adapt the work process to the required working conditions of the workplace.			
	Technical measures for preventil exposure:	ng	See Section 6			

SECTIO	SECTION 9. Physical and chemical properties					
9.1.	Information on basic physical and chemical properties					
		Value	Method			
	Physical state:	powder	No information available			



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	Colour:	dark green	No information available	
	Odour/odour threshold:	odourless/no information available	No information available	
	Melting point / freezing point:	No information available	No information available	
	Boiling point or initial boiling point and boiling range:	No information available	No information available	
	Flammability:	No information available	No information available	
	Lover 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	
2.	Other information			

SECTION	SECTION 10. Stability and reactivity				
10.1.	Reactivity:	No information available			
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:	Strong oxidizing agents			
10.4.	Conditions to avoid:	No information available			
10.5. Incompatible materials:		No information available			
10.6.	Hazardous decomposition products:	No information available			

SECTIO	SECTION 11. Toxicological information						
11.1.	11.1. Information on toxicological effects						
	Acute toxicity:						
Route o		Method	Species	Dose LD ₅₀ /LC ₅₀	Exposure period	Result	



available

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

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Trading name	•	M	ETHYLENI	GREEN, C.I.	52020	······
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Oral exposure: No information available		No inforr		information	No inform	nation -
Skin contact:	No information available	No inforr available		information ailable	No informavailable	nation -
Inhaling:	No information available	No inforr available		o information ailable	No inform available	nation -
Specifi	c target organ toxicity	– single expos	sure (STOT S	SE):		
<u> </u>	Specific e	fects		Target organ		Note
Oral exposure:	No information ava			nation available	-	
Skin contact:	No information ava	nilable	No inforr	nation available	-	
Inhaling:	No information ava	ilable	No inforr	nation available	-	
Aspira	tion hazard:	No ir	nformation	available		
Irritatio	on and corrosion					
<u> </u>	Exposure ti	me S	pecies	Evaluation	Method	Note
Skin corrosion/irritat	No inform		nformation	-	No information available	No informatio
Serious eye damage/irritation	No informon available	No information available		-	No information available	No informatio
Sensiti	zation					
Skin contact:	No information a	vailable				
Inhaling:	No information a					
Sympt	oms related to the phy	sical, chemical	and toxico	logical characte	eristics	
Oral exposure:	No information a	vailable				
Skin contact:	No information a	vailable				
Inhaling:	No information a	vailable				
Eye contact:	No information a	vailable				
Repea	ted dose toxicity (suba	cute, subchron	nic, chronic)			
- 1 1-	Dose	exposure ime	Species	Method	Evaluation	Note
Subacute oral	No intermation	No nformation	No informatio	No on informati	No ion information	1 -

available

available

available

available



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Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhaling toxicity	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 toxicity	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 toxicity	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 t	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 inhaling toxicity	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal toxicity	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal toxicity	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CLAD CC .	,		1	
(N/ID Attacte	/carcinoaanicit	ty multagonicity	roproductivo tovicity)	
CIMIL CHECTS	(carcillou c ille)	.v. mutau c mencity.	TEDIOURCHIVE LOXICITY	
	(.,,,,,	reproductive toxicity)	

Carcinogenicity:	No information available
Mutagenicity in-vitro:	No information available



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Genotoxicity:		No information available			
Mutage	nicity <i>in-vivo</i> :	No information	No information available		
Germ ce	ell mutagenicity:	No information	n available		
Reprodu	uctive toxicity:	No information	n available		
			1		
	Summary of evaluation of the CI	MR properties:	No information available		
11.2.	Information on other hazards:				
11.2.1.	Endocrine disrupting properties:				
	The substance/mixture does components considered to ha disrupting properties according Article 57(f) or Commission regulation (EU) 2017/2100 or Regulation (EU) 2018/605 at levingher.	ve endocrine ig to REACH in Delegated Commission			
11.2.2.	Other informations:				
	-				

SECTION 12. Ecologi	SECTION 12. Ecological information							
12.1. Toxicity	12.1. Toxicity							
Acute (short-term) toxicity	Dose	Exposure period	Species	Method	Evaluation	Note		
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-		
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-		
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-		
Microorganisms	-	-	-	-	-	-		
Chronic (long-term) toxicity	Dose	Exposure period	Species	Method	Evaluation	Note		
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-		
Crustacea:	EC ₅₀	48 hours	No information	No information	No information	-		



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			available	available	available	
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Microorganisms	-	_	-	_	-	-

12.2. Persistence and degradability

Abiotic degradation

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

Biodegradation

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

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	рΗ	°C	Method	Evaluation	Note
No informatio n available	No information available	_	-	No information available	No information available	No information available

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
No information available				
			,	



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	Value	Dose	Exposure period	Spe	ecies	Metho	od	Evaluation	Note
Chronic toxicity on fish LC ₅₀		No informati on available	No inform availal		No informa on availabl	iti i	No nformation available	-	
Chronic toxicity on crustacea (Daphnia)		EC ₅₀	No informati on available		i on		iti i	No nformation available	-
12.4.	Mobility in so	oil							
		edicted distribut	ion in environ	mental	compartn	nents:			
	No informati								
	Surface tensi	on:							
	Value	°C	Concent	ration	M	lethod			Note
	No information available	No information available	No inform available	nation	No info			-	
	Adsorption	description							
	Adsorption /	coefficient							
Transpo	ort	ry's constant	log Kow	Εν	vaporation	n rate	M	1ethod	Note
Soil-wa	ter No availabl		No information available		o inform vailable		No i availal	nformation ble	-
Water-a	air No availabl	information e	No information available		o inform vailable		No i availal	nformation ble	-
Soil-air No information available		No information available				No information available		-	
12.5.		T and vPvB asse	ssment						
	No informati	on available							



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	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7.	Other adverse effects
	No information available

SECTION	l 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:
	No information available
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. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport informati	on
Transporting/shipment by	road (ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions 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:	-
Environmental hazard(s):	-
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:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by sea (IN	MDG)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
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:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Further information: -	

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



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	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; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	Information according 1999 guideline)	0/13/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, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment	t
	None	

SECTIO	SECTION 16. Other information			
16.1.	Indication of changes:	-		
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative		
16.3.	Key literature references and	-		



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Trading name:	METHYLENE GREEN, C.I. 52020				
Product code:	MEG-P-X**	Revision date:	21 Dec 2022	Version:	3

	source of data:		
16.4.	Relevant H statements (number and full text)		
	H: -	-	
16.5.	Training advice:	-	
		** "X" in the product code marks different volumes (different packagings of the product)	
16.6.	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.	

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Exposure scenario resulting to Chemical safety assessment