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Trading name:		LUGOL'S SOLUTIO	N, M.I.F.		
Product code:	LUGM-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

SECT	Product identifier					
	Trading name:	LUGOL'S SOLUTION, M.I.F.				
	Chemical name:	-	-			
	Catalogue number:	LUGM-OT-X	LUGM-OT-X**			
1.2	Relevant identified use	Relevant identified uses of the substance or mixture and uses advised against				
	Uses:		For use v	with M.I.F. kit.		
	Uses advised against:		Only the	identified uses are advised.		
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.			
1.3	Details of the supplier of the safety data sheet					
	Supplier:		BioGnost Ltd.			
	Address:		Medjugorska 59, Zagreb			
	Telephone number:		+385 1 2409997			
	Telefax.:		+385 1 2404039			
	e-mail of competent p	erson:	<u>msds@biognost.hr</u>			
	National contact:		-			
1.4	Emergency telephone	Emergency telephone number				
	National Protection an	d Rescue Dire	ectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	SECTION 2. Hazards identification					
2.1	Classification of the substance or mixture					
2.1.1	Classification according to Regi	ulation (EC) No 12	1272/2008 (CLP)			
	Hazard class and catego	ory code:	Hazard statements*:			
	Not identified as hazardous sub	ostance.	-			
2.1.2.	Additional information					
	-					
*For ful	l text of Hazard- and EU Hazard-	statements: see S	SECTION 16			
2.2	Label elements					
	Product identification:	LUGOL'S SOLUT	ition, m.i.f.			
	Identification number: -					
	Authorization number:	-				
	Hazard pictograms:	-				



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	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	Endocrine Disrupting Prope	rties:
	No known endocrine disrupti	ng properties
	Results of PBT and vPvB as PBT or a vPvB.	sessment: According to the results of its assessment, this substance is not a

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)
-	-	-	Contains no hazardous substances	-

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



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	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.		
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.		
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.		
4.3	Indication of any immediate medical attention and special treatment needed			
	-			

SECTI	ON 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	water spray, dry powder, CO_2 or alcohol resistant foam			
	Unsuitable extinguishing media:	Water with full jet			
5.2	Special hazards arising from the substance or mixture				
	Hazardous combustion products:	no information available			
5.3	Advice for firefighters	Advice for firefighters			
	Use a self-contained open-circuit co	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 not contaminate the environment with extinguishing media.				

SECTION 6. Accidental release measures					
6.1	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contac 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:				
	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 protective barrier or barriers made of similar materials.			



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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:	information: Secure proper ventilation. Do not use incompatible materials (see Section 10).		
6.4	Reference to other sections			
	See Section 7 for information on safe handling.			
	See Section 8 for information on personal protection equipment.			
	See Section 13 for disposal information.			

SECTIO	ON 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:		Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.		
	Measures to prevent aerosol and dust generation	n:	Secure proper ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:		Protect against electrostatic charges.		
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. Th	oroughly was	sh hands after work and before eating.		
7.2	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions: well ve		ghtly closed and upright set containers in a ated storage rooms at temperatures ranging 25 °C. Protect from heat and direct sunlight.		
	Packaging materials:	Manufacturer's original packaging.			
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.			
	Advices for storage equipment: must be		ge must be made of hard material; floors esistant to chemicals. There must be no drain Ily leads into sewage system. Secure proper n.		



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	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Expos	ure contro	ols/perso	onal protec	tion				
8.1 Control p	arameters							
Substance					cupational exposure limit alues/short term values		Biolo	Biological limit values
				p	opm	mg/m ³		
-			-		-	-	-	
	1							
Substance name:	-	1				1		
EC No:	-	CAS No	-					
DNEL								
				Ind	ustrial			
Route of	Αςι		Acu			Chronic		Chronic
exposure:	effect	local	effect sys	stemic		effect local		effect systemic
Oral	-		-		-		-	
Inhalation	-		-		-		-	
Dermal	-		-			-		
Critical physical pa	rameters: s	solubility,	flammabili			-		
			1	Cor	nsumer			
Route of		cute	Acu			Chronic		Chronic
exposure:	effec	t local	effect sy	stemic		effect local		effect systemic
Oral	-		-		-		-	
Inhalation	-		-		-		-	
Dermal	-		-		-		-	
PNEC								
Environmental protection target					PNEC			
Fresh water					no information available			
Freshwater sediments					no information available			
Marine water					no information available			
Marine sediments					no information available			



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Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	no information available
Air	no information available

0.0					
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 prevent exposure:		In accordance with Section 7.		
	Organisational measures to preve exposure:	nt	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent ex	posure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.		
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.			
8.2.2.2.	Skin protection				
	Hand protection:	-	otective gloves have to satisfy the specification of ation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 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:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) acording to EN 14387) used when concentration levels exceed GVI.			
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		



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Structural measures to prevent exposure:	Use modern equipment.
Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
Technical measures to prevent exposure:	See Section 6

1	Information on basic physical and	chemical properties	
		Value	Method
	Physical state:	liquid	No information available
	Colour:	dark brown	No information available
	Odour/odour threshold:	characteristic/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
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n- octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
.2	Other information		

SECTION 10. Stability and reactivity				
10.1	Reactivity:	See subsections 10.3 through 10.5.		



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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	Condition	s to avoid:	No information available					
10.5	Incompat	ible materials:	No information available					
10.6	Hazardou	s decomposition products:	No information available					

	oxicological informati ation on hazard classes		n Requ	lation (EC) No 127	72/2008	
	toxicity:		integu		2,2000	
Route of exposure:	Method	Species	Dc	ose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure ti	ime Results
Oral:	No information available	-	-	information lable	-	-
Dermal:	No information available	-		information lable	-	-
Inhalation:	No information available	-	-	information lable	-	-
Specifi	c target organ toxicity -	- single expc	osure (S	TOT SE):		
	Specific	c effects		Target o	organ	Note
Oral:	No information av	vailable		No information available		-
Dermal:	No information av	vailable		No information	-	
Inhalation:	No information av	vailable		No information	available	-
Aspirat	tion hazard:	Ν	o inforr	nation available.		
Irritatio	on and corrosion					
	Exposure 1	time	Spec	ies Evaluati	on Method	Note
Skin corrosion/irritat	ion:	-		-	-	-
Serious eye damage/irritatio	on -	-		-	-	-
Sensiti	zation					
Skin sensitizatio	on: No infor	mation avail	able.			
Respiratory sen	sitization: No infor	mation avail	able.			



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Oral exposure:	No informati	on available.				
Dermal exposure	: No informati	on available.				
Inhalation expos	ure: No informati	on available.				
Eye exposure:	No informati	on available.				
Repeate	ed dose toxicity (sub	acute, subchro	onic, chronic)			
	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	-



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Tradin	g name:		Page 10 of 16 LUGOL'S SOLUTION, M.I.F.						
	t code:	LUGM-OT-X**		of compilation:	21 Dec 2022	Version:	4		
Subacu	te oral	No information av	vailable	No i	nformation available	-			
Subacu	te dermal	No information av	vailable	No i	nformation available	-			
Subacu	te inhalatior	No information av	vailable	No i	nformation available	-			
Subchro	onic oral	No information av	vailable	No i	nformation available	-			
Subchro	onic dermal	No information av	vailable	No i	nformation available	-			
Subchro	onic inhalati	on No information av	vailable	No i	nformation available	-			
Chronic oral No information avai			vailable	No i	nformation available	-			
Chronic	dermal	No information av	vailable	No i	nformation available	-			
Chronic	inhalation	No information av	vailable	No i	nformation available	-			
		ity <i>in vivo</i> : mutagenicity: ive toxicity: of evaluation of t	Bas Bas	sed on available da sed on available da sed on available da	ata, the classification ata, the classification ata, the classification ata, the classification ole data, the classific	criteria are not r criteria are not r criteria are not r	met. met. met.		
11.2		n on other hazards:							
11.2.1.		disrupting properties:		****					
	componer disrupting Article 57 regulation	ance/mixture does no its considered to have properties according 7(f) or Commission (EU) 2017/2100 or Co (EU) 2018/605 at levels	endocrine to REACH Delegated ommission						
	-	rmation:		:					

SECTION 12. Ecologic	al informat	ion				
12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note



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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 ı	olants	IC ₅₀	4 days	No information available	No information available	No information available	-
Other organism	าร	-	-	-	-	-	-
Chronic (long-t toxicity	erm)	Dose	Exposure time	Species	Method	Evaluation	Note
Fish		LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:		EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic p	olants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organism	าร	-	_	-	-	-	-
				·		·	
12.2 Persist	ence a	nd degradab	ility				
Abioti	c degra	dation					
	De	gradation ha	If-lives	Method	Evaluatio	n	Note
				No information	No informatio	n	

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	-
Biodeg	gradation			
% Degradatio	on Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available



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12.3	Bioaccur	nulative	potential									
			' artition coef	ficient (log Kow)						
Valu	ue C	oncentra	ation p	рΗ	°C Met		bd	Evalua	ation		Note	
-	-		-		-	-		-		_		
	Bioconce	entration	n factor (BCF)								
١	Value		Species	,	1	Method		Evaluatio	on		Note	
	ormation	No		nation		ormation		No information	on	_		
availab	ole	availa	able		availab	le	ä	available				
	Chronic	ecotoxic	ity									
	Value		Dose		osure Spec		ecies Metł		Method Evalu		Note	
				No	ime	No		No	No			
Chroni	c toxicity o	n fish	LC ₅₀	infor	mation	informat	ion i	nformation	inform		-	
				avail	able	available		available	availab	le		
	c toxicity o		EC ₅₀	No infor	mation	No informat		No No information information		ation	-	
crustac	ea (Daphn	<i>(u</i>)		avail	able	available	ä	available	availab	le		
10.4	N 4 1 111	• •1										
12.4	Mobility Known o		ted distribut	ion in 4	anvironm	oental com	nartm	ents:				
	No infor	-					partin	crits.				
	Surface t	ension:										
	Value	2	°C	C	oncentra	ation		Method			Note	
	No informat available	ion ir	lo nformation vailable		informa ailable		o infor ailable	rmation e	-			



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T	Adsorption / de	oefficient				
Transpo	ort	s constant	log Kow	Evaporation rate	Method	Note
Soil-wa	iter No available	information	No information available	No information available	No information available	-
Water-a	air No available	information	No information available	No information available	No information available	-
Soil-air	No available	information	No information available	No information available	No information available	-
12.5	Results of PBT a	and vPvB asses	sment			
	according to RI	EACH Article 5		onents considered to n Delegated regulat igher.		
12.6.	Endocrine disru	pting properti	es			
	according to RI	EACH Article 5	•	onents considered to n Delegated regulat igher.		
12.7	Other adverse	effects				
	No further relev	vant informatio	on available.			
SECTIO	ON 13. Disposal	consideration	s			
	Waste treatm		<u> </u>			
13.1		ient methous				
13.1		lent methods				
	Product/Pack	aging disposa	:			
		aging disposa		rized by the Ministr	y of Environmental	and Nature
13.1.1.	Submit for di Protection.	aging disposa sposal to the le			y of Environmental	and Nature
13.1.1.	Submit for di Protection.	aging disposa sposal to the le /waste designa	egal person autho tions according to			
13.1.1.	Submit for di Protection. Waste codes, 15 01 10*: Pa substances	aging disposa sposal to the le /waste designa	egal person autho tions according to ontains residual ha	o Law:		
13.1 13.1.1. 13.1.2. 13.1.3.	Submit for di Protection. Waste codes, 15 01 10*: Pa substances	aging disposa sposal to the lo /waste designa ckaging that co ent – relevant	egal person autho tions according to ontains residual ha	o Law:		
13.1.1.	Submit for di Protection. Waste codes, 15 01 10*: Pa substances Waste treatm No informatio	aging disposa sposal to the lo /waste designa ckaging that co ent – relevant	egal person autho tions according to ontains residual ha information:	o Law:		



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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:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information: -	

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture		
	EU regulations		
	Authorization and/or restrictions of use		
	Authorizations:	-	
	Restrictions:	-	
	Other EU regulations:	 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII); 	



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None

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 source of data:	-		
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classification		Classification procedure		
-		-		
16.5.	Relevant H statements (number and full text)			
	H: -	-		
16.6.	Training advice:	-		
16.7.	Further information:** "X" in the product code marks different volumes (different packagings of the product)We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to chemical safety assessment