

### **BIOGRAM 4 KIT**

The kit contains:

Gram Crystal violet 1% solution Gram Lugol solution, stabilized Gram Decolorizer solution 2 Gram Safranin solution



#### **SAFETY DATA SHEET**

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

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Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION				
Product code:	GC1-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

SECTI	ON 1: Identification of t	he substance	e/mixture	and of the company/undertaking	
1.1	Product identifier	Product identifier			
	Trading name:	GRAM CRY	STAL VIOL	ET 1% SOLUTION	
	Chemical name:	-			
	Catalogue number:	GC1-OT-X*	*		
1.2	Relevant identified use	s of the subs	tance or m	nixture and uses advised against	
	Uses:		For use	in BioGram 4 Gram bacteria staining kit.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses advis	ed against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplier	of the safety	data shee	t	
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997 +385 1 2404039 msds@biognost.hr		
	Telefax.:				
	e-mail of competent p	erson:			
	National contact:		-		
1.4	Emergency telephone	number			
	National Protection an	d Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards identification				
2.1	Classification of the substance	or mixture			
2.1.1	Classification according to Regu	ulation (EC) No 12	272/2008 (CLP)		
	Hazard class and catego	ory code:	Hazard statements*:		
	Flam. Liq. 3		H226		
	Aquatic Chronic 3		H412		
2.1.2.	Additional information				
	-				
*For ful	l text of Hazard- and EU Hazard-	statements: see S	ECTION 16		
2.2	Label elements				
	Product identification: GRAM CRYSTAL VIOLET 1% SOLUTION				
	Identification number: -				
	Authorization number:	-			



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	Hazard pictograms:	GHS02
	Signal word:	Warning
	Hazard statements:	<ul><li>H226 Flammable liquid and vapor.</li><li>H412 Harmful to aquatic life with long lasting effects.</li></ul>
	Precautionary statements:	<ul> <li>P210 Keep away from heat/sparks/open flames/hot surfaces Do not smoke.</li> <li>P233 Keep container tightly closed.</li> <li>P273 Avoid release to the environment.</li> <li>P280 Wear protective gloves/protective clothing/eye/protection/face protection.</li> </ul>
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	Results of PBT and vPvB ass PBT or a vPvB.	

SECTION 3. Co	SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)	
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610- 43-0147	10 - 20 %	ethanol	Flam. Liq. 2; H225	
548-62-9/ 208-953-6/ 612-204-00-2	-	≤1 %	[4-[4,4'-bis(dimethylamino)benzhydry lidene] cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride	Carc. 2; H351	
108-95-2/ 203-632-7/ 604-001-00-2	01-2119471329- 32-xxxx	< 1 %	phenol	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Skin Corr. 1B; H314 Muta. 2; H341 STOT SE 2; H373	



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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				
	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.			

SECTIO	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 substance or mixture			
	Hazardous combustion products:	Mixture with combustible ingredients. Forms explosive mixtures with air at elevated temperatures. Development of hazardous combustion gases or vapours possible in the event of fire. Vapours are heavier than air and may spread along floors.		



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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 not contaminate the environment with extinguishing media.

SECTIO	ON 6. Accidental release meas	sures		
6.1	Personal precautions, protective equipment and emergency procedures			
6.1.1.	For non-emergency personne	:1		
	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:			
	Do not let product enter drains. Risk of explosion.			
6.3	Methods and material for con	itainment 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 Environmenta and Nature Protection. After disposal of the products, wash the area 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.		
		on personal protection equipment.		
	See Section 13 for disposal in	See Section 13 for disposal information.		

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



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	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	on:	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	o not eat, drink or smoke in the workspace. Thoroughly was			
7.2	Conditions for safe storage, including any incon	itions for safe storage, including any incompatibilities			
	Technical measures and storage conditions: well ventila		ghtly closed and upright set containers in a ated storage rooms at temperatures ranging 25 °C. Protect from heat and direct sunlight.		
	Packaging materials:	Manufactu	turer'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 re	ge must be made of hard material; floors esistant to chemicals. There must be no drain ly leads into sewage system. Secure proper i.		
	Further information on storage conditions:	and do no	ice the unused material in the storage room t use empty containers for storing other Do not store with incompatible materials on 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	•	exposure limit t term values	Biological limit values		
		ppm	mg/m³			
Ethanol	64-17-5	1000/-	1900/-	-		
Phenol	108-95-2	2/4	8/16	120 mg/g of creatinine (0.14 mol/mol of creatinine), end of shift, urinary excretion		



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Substance name:	<b>–</b>					
EC No:	- CAS	No:	_			
DNEL						
			Ind	lustrial		
Route of	Acute		Acute		Chronic	Chronic
exposure:	effect local	effe	ect systemic		effect local	effect systemic
Oral	-	-		-		-
Inhalation	1900 mg/ m <sup>3</sup> (ethanol) 16 mg/ m <sup>3</sup> (phenol)	-		-		380 mg/m³ (ethanol) 8 mg/m³ (phenol)
Dermal	-	-		-	I	343 mg/kg (ethanol) 1.23 mg/kg (phenol)
Critical physical para	ameters: solubili	y, flamn	nability, cor	rosivity:	-	
			Cor	nsumer		
Route of	Acute		Acute		Chronic	Chronic
exposure:	effect local	effe	ect systemic		effect local	effect systemic
Oral	-	-		-		87 mg/kg (ethanol) 0.5 mg/kg (phenol)
Inhalation	950 mg/ m <sup>3</sup> (ethanol)	-		-		114 mg/m³ (ethanol) 0.452 mg/m³ (phenol)
Dermal	-	-		-		206 mg/kg (ethanol) 0.5 mg/kg (phenol)
PNEC						
Environmental prote	ection target			PNEC		
Fresh water				0.96 mg/l (ethanol) 0.0077 mg/l (phenol)		
Freshwater sedimen	ts			3.6 mg/kg (ethanol) 0.09125 mg/kg (phenol)		
Marine water			0.79 mg/l (ethanol) 0.00077 mg/l (phenol)			
Marine sediments		2.9 mg/kg (ethanol) 0.00915 mg/kg (phenol)				
Food chain				380-720 ı	mg/kg kg (ethano	)
Microorganisms in s	sewage treatmer	t		580 mg/l 2.1 mg/l (		
Soil (agricultural)				_	kg (ethanol) /kg (phenol)	



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Air			no information available		
8.2	Evenosura controle				
8.2.1.	Exposure controls  Appropriate engineering controls				
0.2.1.	Appropriate engineering controls		Has the grand out in small contileted as a grant Has grant and		
	Substance/mixture related measures prevent exposure during identified u		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.		
822	Organisational measures to prevent exposure:		Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent exposure:		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:	evels c	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 cor 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:	ootwe entire f mpern	everyday work use cotton clothing (EN 340) and suitable ar, such as rubber boots (EN 20345) or shoes that cover the foot. In case of spilling hazard, use clothing made of neable material suitable for protection from liquid chemicals PVC, himex) and footwear made from the same material.		
8.2.2.3.	Respiratory protection:	with a f	tive full face mask (EN 136) or half mask (EN 140) equipped filter for organic vapors, type "A" (boiling point >65°C) ng 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				



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Substance/mixture related measures to prevent exposure:	See Section 6
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

	Information on basic physical and	chemical properties	
		Value	Method
	Physical state:	liquid	No information available
	Colour:	purple	No information available
	Odour/odour threshold:	phenol like/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lover and upper explosion limit:	No information available	No information available
	Flash point:	49°C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
)	Other information		

#### **SECTION 10. Stability and reactivity**



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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 decompostion products known.

11.1 Inform	ation on haz	ard classes as	defined in	Regulation	(EC) No 1272/200	)8			
	toxicity:				<u>· · · · · · · · · · · · · · · · · · · </u>				
Route of exposure:	Meth	od Spec	cies LD	Dose <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time		Results		
Oral:	-	ra	t	LD <sub>50</sub>	-	10.470	0.470 mg/kg (ethanol)		
Dermal:	-	ra	t	LD <sub>50</sub>	_	660 mg	g/kg (phenol)		
Inhalation:	-	ra	t	LC <sub>50</sub>	4 h	124.7 r	ng/l (ethanol)		
Specifi	c target orga	n toxicity – si	ngle exposu	ire (STOT S	E):				
Specific e			fects		Target organ		Note		
Oral:	rmation avail	able No in		information available		-			
Dermal:	Dermal: No information avai			No i	nformation availal	ole	-		
Inhalation:	No info	rmation avail	able	No i	nformation availal	ole	_		
Aspirat	ion hazard:		No	nformation	formation available.				
:									
Irritatio	on and corro	sion							
	Ex	oosure time	Species	Evaluati	on Method		Note		
Skin corrosion/irritat	ion:		in vitro study	_	OECD 431	cause	es burns (phenol)		
Serious eye damage/irritation	on -		rabbit	<b>-</b>	OECD 405	corro	sive (phenol)		
Sensiti									
Skin sensitization	n:	No informa							
Respiratory sens	sitization:	No informa	tion availab	le.					



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Oral exposure:		No informati	on available.							
Dermal exposure	<b>:</b>	No informati								
Inhalation expos			ition available.							
Eye exposure:		No informati								
, ,										
Repeate	d dos	se toxicity (sub	acute, subchro	onic, chronic)						
		Dose	Dose Exposure time Species Method Evaluation				Note			
Subacute oral		information lable	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		information lable	No information available	No information available	No information available	No information available	-			
Subchronic oral	No avai	information lable	No information available	No information available	No information available	No information available	-			
Subchronic dermal		information lable	No information available	No information available	No information available	No information available	-			
Subchronic inhalation		information lable	No information available	No information available	No information available	No information available	-			
Chronic oral	1	information lable	No information available	No information available	No information available	No information available	-			
Chronic dermal		information lable	No information available	No information available	No information available	No information available	-			
Chronic inhalation		information lable	No information available	No information available	No information available	No information available	-			
i										
Specific	targe	t organ toxicit	<u> </u>	xposure (STOT						
			Specific effection available	ts	Target o		Note			



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Subacut	te dermal	No information available			No information available	-			
Subacut	te inhalation	No information available			No information available	-			
Subchro	onic oral	No information available			No information available	-			
Subchro	onic dermal	No information available			No information available	-			
Subchronic inhalation No information available					No information available	-			
Chronic	oral	No information available			No information available	-			
Chronic	dermal	No information available			No information available	-			
Chronic	inhalation	No information available			No information available	-			
	CMR effects (c	arcinogenicity; mutagenicit	v: repro	oductive t	oxicity)				
	Carcinogenicity:			Based on available data, the classification criteria are not met.					
	Mutagenicity in vitro:			Based on available data, the classification criteria are not met.					
	Genotoxicity:		Based	on availa	ble data, the classification o	criteria are not met.			
	Mutagenicity i	n vivo:	Based on available data, the classification criteria are not met.						
	Germ cell muta	agenicity:	Based on available data, the classification criteria are not met.  Based on available data, the classification criteria are not met.						
	Reproductive t	oxicity:							
	Summary of properties:	evaluation of the CN		et.	available data, the classific	ation criteria are not			
11.2	Information or	other hazards:							
11.2.1.	Endocrine disr	upting properties:							
	No known end that affect hum	docrine disrupting propert nan health.	ties						
11.2.2.	Other informat	tions:							
	_								

SECTION 12. E	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	Leuciscus idus (Golden orfe; ethanol) Oncorhynchus mykiss (rainbow trout; phenol)	-	-	8.140 mg/l (ethanol) 5.0 mg/l (phenol)					



12.3

Bioaccumulative potential

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Crustacea:	EC <sub>50</sub>			inia magna er flea)	-		_	7.800 mg/l (ethanol) 3.1 mg/l (phenol)
Algae/aquatic plants	IC <sub>50</sub>	7 days	green algae		algae -		-	5.000 mg/l (ethanol) 6.500-13.000 mg/l (ethylene glycol) 61.1 mg/l (phenol)
Other organisms	-	-	-		-		<b>–</b>	-
Chronic (long- term) toxicity	Dose	Exposure time	Species		M	ethod	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available		_		-	-
Crustacea:	EC <sub>50</sub>	18 hours	No information available		-		-	-
Algae/aquatic plants	IC <sub>50</sub>	/2 hours	No information available		-		-	-
Other organisms	-	-	-				-	-
	ence and	degradability tion						
	ī							
	Degra	adation half-live	es	Method		E <sup>,</sup>	valuation	Note
Marine water				Method No information available	า		ormation	Note -
Marine water Fresh water	No info	adation half-live	ole	No information		No info	ormation ble ormation	
Fresh water	No info	adation half-live	ole ole	No information available  No information	า	No info availab No info availab	ormation ole ormation ole ormation	-
	No infor	adation half-livermation availab	ole ole ole	No information available  No information available  No information	า	No info availab No info availab No info availab	ormation ole ormation ole ormation ole ormation ole	-
Fresh water Air Soil	No infor	ndation half-livermation availab rmation availab rmation availab	ole ole ole	No information available No information available No information available No information available	า	No info availab No info availab No info availab	ormation ole ormation ole ormation ole ormation ole	-
Fresh water Air Soil	No information No information	ndation half-livermation availab rmation availab rmation availab	ole ole ole	No information available No information available No information available No information available	า	No info availab No info availab No info availab	ormation ole ormation ole ormation ole ormation ole	-
Fresh water  Air  Soil  Biode	No information No information No information No	rmation half-liver rmation availab rmation availab rmation availab rmation availab	ole ole ole	No information available No information available No information available No information available available	า	No info availab No info availab No info availab	ormation ole ormation ole ormation ole ormation ole ormation ole aluation ormation	-



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	Octa	anol-w	ater pai	rtition coe	fficient	(log Kow)							
Va	lue	С	oncentr	ation	рН	°C	Ме	ethod		Evalua	ation		Note
-		-		-					-				paccumulation is t expected
					·	·						·	
	Bioc	oncen	tration	factor (BC	F)								
V	alue/			Species		Met		l	E۱	Evaluation			Note
	No information No infavailable available		_	mation	No info		n	No info		on	-		
	Chrc	onic ec	otoxicit	ту									
	Value Dose				oosure ime	Spe	ecies	Meth	nod	Eval	uation	Note	
Chronic toxicity on fish LC <sub>50</sub>				information		1		ation lle	No inforn availa	nation ble	-		
	Chronic toxicity on crustacea ( <i>Daphnia</i> )			information i				ation le	No information available		-		
					·								·
12.4	Mob	oility ir	n soil										
	Knov	wn or	predicte	ed distribu	tion in	environme	ental c	ompart	ments:				
	No i	nform	ation av	/ailable									
	Surf	ace te	nsion:										
	\	/alue		°C	C	oncentrat	tion		Metho	od			Note
		rmatio lable		ormation ailable		informat ailable	ion	n No information available		n	-	-	
	Adso	orptio	n / desc	orption									
Transpo	ort		A/D coef enry's co		lo	og Kow	Ev	/aporati	on rate	Method		t l	Note
Soil-wa	ter	No availa		nformation	No i	nformatio able		o inform ailable	No informatic available		tion	-	



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Water-a	No information available	No information available	No information available	No information available	_					
Soil-air	Noinformation availableNo information availableNo information availableNo information available									
12.5		Results of PBT and vPvB assessment								
	Based on available data, the	product does not o	contain any PBT or	vPvB substances.						
12.6.	Endocrine disrupting propert	ies								
	Based on available data, does		crine disruptors.							
	·		·							
12.7.	Other adverse effects									
_	No further relevant informati	on available.								
SECTIO	N 13. Disposal consideration	ıs								
13.1	Waste treatment methods									
	:									
13.1.1.	Product/Packaging disposa									
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.									
	1 Totection.									
13.1.2.	Waste codes/waste designa	ations according to	o Law:							
	15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous									
	substances									
13.1.3.	Weste treatment relevant	information								
15.1.5.	Waste treatment – relevant  No information available	iniormation.								
	140 imormation available									
13.1.4.	Sewage disposal – relevant	information:								
	Waste must not be dispose		ge system.							
	•		-							
13.1.5.	Other disposal recommend	ations:								
	authorized by the ministry	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.								
13.1.6.	Relevant Community provis	sions:								
	Disposal must be made acc	ording to official r	egulations.							



#### **SAFETY DATA SHEET**

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

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Trading name:		<b>GRAM CRYSTAL VIOLET 1% SOLUTION</b>				
Product code:	GC1-OT-X**	Date of compilation:	21 Dec 2022	Version:	5	

SECTION 14 TRANSPORT INFORMATIO	DN
Transporting/shipment by road (	ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	Ш
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (R	ID)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	Ш
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IN	MDG)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	Ш
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3



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Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION				
Product code:	GC1-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Packing group:		III
Environmentally hazardous:		-
Special precautions for u	user:	-
Further information:	•	ovision 144 – An aqueous solution containing 24% or less alcohol by ubject to classification.
rurther information.	IATA: Special Provision A58 - An aqueous solution containing 24% or less alcohol by volume is not subject to classification.	

	ON 15. Regulatory informa						
15.1	Safety, health and environmental 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						



#### **SAFETY DATA SHEET**

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

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Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION				
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SECTIO	ON 16	. Other information				
16.1	Indi	cation of changes:		-		
16.2	Abbreviations and acronyms:		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.	Key literature references and source of data:		and	-		
16.4.		sification and proced 2/2008 (CLP)	ure us	ed to derive the classification for mixture according to Regulation (EC)		
Classifi	catior	1	С	lassification procedure		
-			-			
16.5.	Rele	evant H statements (n	umber	and full text)		
		H225	Highl	y flammable liquid and vapor.		
		H226	Flamı	mable liquid and vapor.		
		H301	Toxic	kic if swallowed.		
		H302	Harm	ful if swallowed.		
		H311	Toxic	in contact with skin.		
		H314	Cause	es severe skin burns and eye damage.		
	H:	H318	Cause	es serious eye damage.		
		H331	Toxic	if inhaled.		
		H341	Suspe	ected of causing genetic defects.		
		H351	Suspe	ected of causing cancer.		
		H373	•	cause damage to organs through prolonged or repeated exposure.		
		H400	Very	toxic to aquatic life.		
		H410	•	toxic to aquatic life with long lasting effects.		
		H412	-	ful to aquatic life with long lasting effects.		
16.6.	Trai	ning advice:	-			



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Trading name:	G	GRAM CRYSTAL VIOLET 1% SOL			
Product code:	GC1-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

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
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Trading name:	GRAM LUGOL SOLUTION, STABILIZED				
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version: 5	

SECTION	ON 1: Identification of	the substance	e/mixture a	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	GRAM LUC	OL SOLUTIO	DN, STABILIZED	
	Chemical name:	-			
	Catalogue number:	GLS-OT-X*	GLS-OT-X**		
1.2.	2. Relevant identified uses of the substance or mixture and uses advised against		xture and uses advised against		
	Uses:		Solution f	or use in BioGram 4 Gram bacteria staining kit.	
	Uses advised against:		Only the i	dentified uses are advised.	
Reason why uses advised against: medical device, registered at the A		evice, registered at the Agency for Medicinal Products and evices and there is no reason to use it for other purposes			
1.3.	Details of the supplie	r of the safety	data sheet		
	Supplier:	В	BioGnost Ltd.		
	Address:	N	Medjugorska 59, Zagreb		
	Telephone number:	+	+385 1 2409997		
	Fax no.:	Fax no.: +:		-385 1 2404039	
	e-mail of competent person: <u>m</u>		msds@biognost.hr		
	National contact:	-			
1.4.	Emergency telephone	number			
	National Protection a	nd Rescue Dir	rectorate:	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 Regula	Classification according to Regulation (EC) No 1272/2008 (CLP)			
	Hazard class and category	/ code: Hazard statements*:			
	Not identified as hazardous substance				
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazard-sta	atements: see Section 16			
2.2.	Label elements				
	Product identification:	GRAM LUGOL SOLUTION, STABILIZED			
	Identification number:	-			
	Authorization no.:	-			
	Hazard pictograms:	-			



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Trading name:	GRAM LUGOL SOLUTION, STABILIZED			
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	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	<b>Endocrine Disrupting Properties:</b>	
	No known endocrine disrupting prop	erties.

SECTION 3. Co	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)	
-	-	-	Contains no hazardous substances	-	

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:  Following eye contact:  Following ingestion:		Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.	
			Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.	
			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	der:	Treat symptomatically.	
4.2.	Most important symptoms a	nd effec	cts, both acute and delayed	
	Following inhalation:		ding to our findings, chemical, physical and toxicological properties of obstance have not been entirely tested.	
	Following skin contact:		ding to our findings, chemical, physical and toxicological properties of obstance have not been entirely tested.	
	Following eye contact:	According to our findings, chemical, physical and toxicological properties the substance have not been entirely tested.		



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Trading name:	GRAM LUGOL SOLUTION, STABILIZED			
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version: 5

	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	
	-	

SECTIO	SECTION 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 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. Remove all sources of 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	s
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

SECTIO	ON 7. Handling and storage					
7.1.	Precautions for safe handling					
7.1.1.	Protection measures					
	Measures to prevent fire:		eep away from sources of heat and ignition. Do ot smoke.			
	Measures to prevent aerosol and dust generati	on: S	ecure proper ventilation.			
	Measures to protect the environment:		revent spilling into the sewage system and raterways.			
	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:	ventila	n tightly closed and upright set containers in a well ted storage rooms, and away from sources of heat, nt, and other incompatible substances.			
	Packaging materials:	Manuf	acturer's original packaging.			
	Requirements for storage rooms and vessels:		away from food and drink. Keep the containers closed.			
	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 9).				
7.3.	Specific end use(s)					



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Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection										
		meters	, р							
Substance					Occupational exposure limit values/short term values		Biological limit values			
						ppm	mg/m³			3
-			-			-		-	No infor	mation available
					•					
Substance name:	-									
EC No:	-		CAS No:	-						
DNEL				•						
					Inc	dustrial				
Pouto of ovno	curo:	A	Acute		Acut	е		Chron	ic	Chronic
Noute of expo	Route of exposure: eff		ect local	effe	ect sys	temic		effect lo	cal	effect systemic
Oral -		-		-			-	-		-
Inhalation	Inhalation -			-			-			-
Dermal		-		-			-			-
Critical physic	al parar	meters: s	solubility, fla	mmabili	ty, cor	rosivity:	-			
		1			Co	nsumer	_			
Route of expo	sure:		Acute		Acut			Chron		Chronic
·		effe	ect local	effect syst		temic	effect local		cal	effect systemic
Oral		-		-			-			-
Inhalation		-		-			-			-
Dermal		-		-			-			-
PNEC										
Environmenta	l protec	ction tar	get			PNEC				
Fresh water						No information available				
Freshwater sediments						No information available				
Marine water						No information available				
Marine sedim	ents					No information available				
Food chain						No information available				
Microorganisi	ms in se	wage tr	eatment			No information available				
Soil (agricultural)				No information available						



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Air			No information available		
8.2.	Exposure controls				
8.2.1.	Appropriate engineering	controls			
	Substance/mixture relate measures to prevent expeduring 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 pr exposure:	event	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 prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.		
8.2.2.	Personal protection equip	ipment			
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN visor.			
8.2.2.2.	8.2.2.2. Skin protection				
			ective gloves must be according to the EU Directive 2016/425/EEC and lard EN 374.		
	Hand protection:		Glove material: nitrile rubber		
			Glove thickness: ≥0.50 mm  Break through time: >480 min		
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) with long s (EN 13034), and shoes that cover the entire foot (EN 10335).		
8.2.2.3.	Respiratory protection:	filter fo	ctive full face mask (EN 136) or half mask (EN 140) equipped with a cor organic vapors, type "A" (boiling point >65°C) acording to EN ) used when concentration levels exceed GVI.		
8.2.2.4.	Thermal hazards:	No inf	ormation available		
8.2.3.	Environmental exposure	controls			
	Substance/mixture relate measures to prevent expe		See Section 6		
	Structural measures to preexposure:	event	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**



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Trading name:	GRAM LUGOL SOLUTION, STABILIZED					
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version: 5		

	Value	Method
Physical state:	liquid	No information available
Color:	yellow/amber	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
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
pH:	No information available	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available

SECTIO	SECTION 10.: Stability and reactivity					
10.1.	Reactivity:	See subsections 10.3 through 10.5.				
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.				
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**



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Trading name:	GRAM LUGOL SOLUTION, STABILIZED						
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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	time	Results
Oral exposure: No information available		-	LD <sub>50</sub>	-		-
Dermal exposure:	No information available	-	LD <sub>50</sub>	_		-
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-		-
Specific targ	get organ toxicity – si	ngle exposure (	(STOT SE):			
	Specif	ic effects	Target	organ		Note
Oral exposure:	No information	available	No information	on available	-	
Dermal exposure:	No information	available	No information	mation available -		
Inhalation exposure:	No information	available	No information available		-	
Aspiration h		THE HITE	rmation available			
	Exposure time	Species	Evaluation	Method		Note
Skin irritation:	-	-	-			
Eye irritation:	-	-	-			
Sensitization	า					
Dermal exposure:	No information avail	able				
Inhalation exposure:	No information avail	able				
Symptoms r	related to the physica	ıl, chemical and	toxicological chara	cteristics		
Oral exposure:	According to our have not been en	•	cal, physical and to	xicological pro	perties	of the substanc
Dermal exposure:	According to our have not been en	_	cal, physical and to	xicological pro	operties	of the substanc
Inhalation exposure:	According to our	findinas, chemi	cal, physical and to	xicological pro	perties	of the substanc



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Trading name:	GRAM LUGOL SOLUTION, STABILIZED						
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version: 5			

FVE EXPOSITE.		o our findings, een entirely test	•	hysical	and toxicolog	ical propert	ies of the substance
Repeate	ed dose toxicity (su	bacute, subchro	onic, chronic	c)			
	Dose	Exposure time	Species		Method	Evaluation	n Note
Subacute oral	Subacute oral No information available		No informatio available	on	No information available	No information available	on -
Subacute dermal	No information available	No information available	No informatic available	on	No information available	No informatio available	on -
Subacute inhalation	No information available	No information available	No informatic available	on	No information available	No information available	on -
Subchronic oral	No information available	No information available	No informatic available	on	No information available	No information available	on -
Subchronic dermal	No information available	No information available	No informatio available	on	No information available	No information available	on -
Subchronic inhalation	No information available	No information available	No informatio available	on	No information available	No information available	on -
Chronic oral	No information available	No information available	No informatio available	on	No information available	No informatio available	on -
Chronic dermal	No information available	No information available	No informatio available	on	No information available	No information available	on -
Chronic inhalation	information information information information information			on -			
Specific	target organ toxic		exposure (ST	OT RE			<b>.</b>
Subacute oral	NIA :af	Specific effects nation available		Target organ			Note
Subacute orai Subacute dermal		nation available			No information available - No information available -		_
Subacute dermai		nation available			formation avai		_
Subchronic oral		nation available			formation avai		_



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Trading name:		GRAM LUGOL SOL	UTION, STABILIZED	
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version: 5

Subchro	onic dermal	No informatio	n available	No information available	-		
Subchro	onic inhalation	nic inhalation No information available		No information available	-		
Chronic	oral No information available			No information available	-		
Chronic	ic dermal No information available			No information available	-		
Chronic	inhalation	No informatio	n available	No information available	-		
	CMR effects (c	arcinogenicity: n	outagenicity; repr	oductive toxicity)			
	Carcinogenicit		1	<u> </u>	ercinogenic effects		
	Carcinogenicity: Current studies on test animals did not indicate carcinogenic effects.  Mutagenicity <i>in-vitro</i> : Current <i>in vitro</i> tests did not indicate mutagenic effects.						
	Genotoxicity:		No information				
	Mutagenicity <i>i</i>	n-vivo:	Current in vivo tests did not indicate mutagenic effects.				
	Germ cell mut		No information				
	Reproductive t	toxicity:	No toxicity or organs.	n reproductive organs was deter	mined in reproductive		
	Summary of ev	valuation of the	CMR properties:	-			
11.2.	Information on other hazards:						
11.2.1.	Endocrine disr	upting propertie	S:				
	No known end	locrine disruptin	g properties that	affect human health.			
11.2.2.	Other informa	tions:					

<b>SECTION 12. Ecological inform</b>	nation
--------------------------------------	--------

#### 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



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Product code: GLS-OT-X** Date of compilation: 14 November 2022 Version: 5	Trading name:	GRAM LUGOL SOLUTION, STABILIZED						
· ·	Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version:	5		

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	-	-	-	-	-	-

#### 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	-

			. •	
Biod	ear	ad:	atı	On.

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

#### 12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

Value	Concentration	рН	°C	Method	Evaluation	Note
-	No information available	-	_	No information available	No information available	-

Value	Species	Method	Evaluation	Note



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Trading		:									Page	12 of 16
aag	name:				GRAM	LUGO	L SOL	UTION,	STABIL	IZED		
Product	code:	GLS-C	)T-X**	D	ate of co	ompila	tion:	14 No	vember	2022	Vers	ion: 5
No inforr available		No availab	inform le	ation	No info availabl		n	No info	ormation le		No inform available	nation
								***************************************				
***************************************	Chronic ed Value	cotoxicity	/ Dose		osure	Spe	cies	Met	hod	Eval	uation	Note
Chronic t	oxicity on	fish	LC <sub>50</sub>	No infor	mation able	No inform availal		No informavailab	ation	No inform availab		_
	oxicity on ( <i>Daphnic</i>		EC <sub>50</sub>	No infor availa	mation able	No inform availal		No inform availab	ation	No inform availab		_
	Mobility in Known or No inform	predicte	d distributi ailable	on in e	environm	ental co	ompart	ments:				
	Surface te											
	Value		°C	C	oncentrat	tion		Metho	od		No	ote
į	No informatic available		ormation ilable		informat ilable	ion	No inf availat	ormation ble	1	-		
	Adsorptio	n / deso	rption									
Transpor	t A	A/D coeff enry's co	ficient	lc	og Kow	Eva	aporati	on rate	Me	thod		Note
Soil-wate	er No availa		formation	No ir availa	nformatio able		inform ailable	nation	No info		n -	
3011-wate			formation	No ir	nformatio		inform	nation	No info		n _	
Water-ai	r No availa			availa	able	avo	ailable			C		



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Trading name:		GRAM LUGOL SOL	UTION, STABILIZED	
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version: 5

12.6.	Endocrine disrupting properties	
	No known endocrine disrupting properties that affect the environment.	
12.7.	Other adverse effects	
	No adverse effects are expected.	
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:	
	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 whe ignition may occur.	nit
13.1.6.	Relevant Community provisions:	
	-	
SECTIO	N 14. Transport information	
	Transporting/shipment by road (ADR)	
UN num	nber: Not subject to transport regulations.	
UN prop	per shipping name: -	
Transpo	ort hazard class(es): -	



				Page 14 of	16
Trading name:		GRAM LUGOL SOL	UTION, STABILIZED		
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version:	5
Packing group:		-			
Environmentally h		-			
Special precaution		-			
	rting/shipment by rai				
UN number:		Not subject to transport	regulations.		
UN proper shippi		-			
Transport hazard	class(es):	-			
Packing group:		-			
Environmentally h	nazardous:	-			
Special precaution	ns for user:	-			
Inland w	aterway transport (A	DN)			
UN number:		Not subject to transport	regulations.		
UN proper shippi	ng name:	-			
Transport hazard	class(es):	-			
Packing group:		-			
Environmentally h	nazardous:	-			
Special precaution	ns for user:	-			
Transpor	rting/shipment by se	a (IMDG)			
UN number:		Not subject to transport	regulations.		
UN proper shippi	ng name:	-			
Transport hazard	class(es):	-			
Packing group:		-			
Environmentally h	nazardous:	-			
Special precaution	ns for user:	-			
Transpor	rting/shipment by air	(ICAO-TI/IATA-DGR)			
UN number:		Not subject to transport	regulations.		
UN proper shippi	ng name:	-			
Transport hazard	class(es):	-			
Packing group:		-			

Further information: The product is not subject to classification.

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

Environmentally hazardous: Special precautions for user:



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Trading name:		GRAM LUGOL SOLUTION, STABILIZED			
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version: 5	

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 (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				

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



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Trading name:		GRAM LUGOL SOL	UTION, STABILIZED	
Product code:	GLS-OT-X**	Date of compilation:	14 November 2022	Version: 5

	1	
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 1272/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)
Classific	cation	Classification procedure
_		-
16.5.	Relevant H statements (numb	per 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	



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Trading name:		GRAM DECOLORIZ	ER SOLUTION 2		
Product code:	GD2-OT-X**	Revision date:	23 Dec 2022	Version:	5

SECTI	ON 1: Identification of	the substance	e/mixture	and of the company/undertaking	
1.1	Product identifier				
	Trading name:	name: GRAM DEC		OLORIZER SOLUTION 2	
	Chemical name:	-			
	Catalogue number:	GD2-OT-X*			
1.2	Relevant identified uses of the substance or mixture and uses advised against				
	Uses:		For use in Gram bacterial staining.		
	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 person:		msds@biognost.hr		
	National contact:		-		
1.4	Emergency telephone number				
	National Protection and Rescue Dire		ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

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 category co	de: Hazard statements*:			
	Flam. Liq. 2	H225			
	Eye Irrit. 2	H319			
	STOT SE 3	H336			
		EUH066			
2.1.2.	Additional information				
	-				
*For fu	ıll text of Hazard- and EU Hazard-stater	ments: see SECTION 16			
2.2	Label elements				
	Product identification: GRA	M DECOLORIZER SOLUTION 2			



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Trading name:	GRAM DECOLORIZER SOLUTION 2				
Product code:	GD2-OT-X**	Revision date:	23 Dec 2022	Version:	5

	Identification number:	-			
	Authorization number:	-			
	Hazard pictograms:	GHS02 GHS07			
	Signal word:	Danger			
	Hazard statements:	<ul> <li>H225 Highly flammable liquid and vapor.</li> <li>H319 Causes serious eye irritation.</li> <li>H336 May cause drowsiness or dizziness.</li> <li>EUH066 Repeated exposure may cause skin dryness or cracking.</li> </ul>			
	Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.			
	Supplemetal hazard information (EU):	-			
2.3	Other hazards				
	The product has no other kno	The product has no other known specific hazards for human or environment.			
	Results of PBT and vPvB asses PBT or vPvB substances.	Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.			
	Endocrine disrupting propert	y: Based on available data, does not contain endocrine disruptors.			

SECTION 3. Composition/information on ingredients							
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)			
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- 0147	40 – 60 %	ethanol	Flam. Liq. 2; H225			
67-64-1/ 200-662-2/ 606-001-00-8	-	50 - 70 %	acetone	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336			

#### **SECTION 4. First aid measures**



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Trading name:	GRAM DECOLORIZER SOLUTION 2				
Product code:	GD2-OT-X**	Revision date:	23 Dec 2022	Version:	5

		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.			
	Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact:	In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 10 minutes). If the symptoms remain, immediately call in ophthalmologist.			
	Following ingestion:	Place the victim in a comfortable position. Rinse the mouth with clean water. If the victim is conscious induce vomiting.  Do not give the victim anything orally, and do not induce vomiting if the victim is unconscious or suffers from convulsions.			
	Self-protection of the first aider:	-			
4.2	Most important symptoms and effects, both acute and delayed				
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.			
	Following skin contact:	Defatting, dry skin.			
	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 media	cal attention and special treatment needed			

SECTI	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Dry powder, alcohol-resistant foam, water spray, carbon-dioxide.			
	Unsuitable extinguishing media:	No information available.			
5.2	Special hazards arising from the su	ubstance or mixture			
	Hazardous combustion products:	No information available.			
5.3	Advice for firefighters				
	Wear full protective clothing and self-contained breathing apparatus. Cool the fire affected containers with water spray. Use water spray to dissipate alcohol vapors.				
5.4	Additional information				



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Trading name:		GRAM DECOLORIZ	ZER SOLUTION 2		
Product code:	GD2-OT-X**	Revision date:	23 Dec 2022	Version:	5

-

SECTIO	ON 6. Accidental release meas	ures			
6.1	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personne	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, vapors and aerosols. Ensure adequate ventilation. Vapors may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.				
6.2	Environmental precautions:				
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.				
6.3	Methods and material for con	tainment and cleaning up			
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.			
6.3.2.	Cleaning up:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal.  During the collection, placement, disposal of the waste, wear appropriate individual protective equipment.  Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).			
6.3.3.	Other information:	Socure proper ventilation. Do not use incompatible materials (see Section			
6.4	Reference to other sections				
	See Section 7 for information on safe handling.  See Section 8 for information on personal protection equipment.				
	See Seedion o for information	on personal protection equipment			

SECTIO	SECTION 7. Handling and storage			
7.1	Precautions for safe handling			
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 wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities		
	Technical measures and storage conditions:	Store in a well-ventilated place, protected from sunlight, away from sources of heat and ignition, in its original, unopened and hermetically sealed packaging, away from oxidizing agents, food, feed and articles of consumption.	
	Packaging materials:	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:	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. Exposure controls/personal protection						
8.1 Control parameters						
Substance	CAS No	·	exposure limit t term values	Biological limit values		
		ppm	mg/m³	-		
Ethanol	64-17-5	1000/-	1900/-	-		
Acetone	67-64-1	500/-	1210/-			
		·				



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Trading name:					
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Substance name:	-								
EC No:	_	CAS No	:	-					
DNEL									
In						I			
Route of	Acu	te		Acute		Chronic		Chronic	
exposure:	effect	local	effe	ct systemi	С	effect local		effect systemic	
Oral	-		-		-			-	
Inhalation	1900 mg (ethanol)		-		-			380 mg/m³ (ethanol) 1210 mg/m³ (acetone)	
Dermal	-		-		-			343 mg/kg (ethanol)	
Citical about all ac		- L. d- 113a	(l	- 1-1114				186 mg/kg (acetone)	
Critical physical par	ameters: s	olubility,	Tiamm	<u> </u>	•				
					nsume			<u> </u>	
Route of exposure:		tute t local	offe	Acute ect systemi	_	Chronic effect local		Chronic effect systemic	
Oral	- enec	t local	-	ect systemi	-	effect local		87 mg/kg bw/day (ethanol)	
	950 m	a/m³	_					114 mg/m³ (ethanol)	
Inhalation	(ethan	_	-		-			200 mg/m³ (acetone)	
Dermal	_		-		_			206 mg/kg (ethanol)	
								62 mg/kg (acetone)	
PNEC									
Environmental prot	ection targ	get			PNEC				
Fresh water					0.96 mg/l (ethanol) 10.6 mg/l (acetone)				
					3.6 mg/kg (ethanol)				
Freshwater sedime	nts				30.4 mg/kg (acetone)				
Marina					0.79 mg/l (ethanol)				
Marine water					1.06 mg/kg (acetone)				
Marine sediments					2.9 mg/kg (ethanol)				
Trialine Seamients					3.04 mg/kg (acetone)				
Food chain		380-720 mg/kg (ethanol)							
Microorganisms in	sewage tre	eatment				ig/l (ethanol)			
			ig/l (acetone)						
Soil (agricultural)			ng/kg (ethanol)						
Air					33.3 mg/kg (acetone) no information available				
,					110 1111				



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8.2	Exposure controls					
8.2.1.	Appropriate engineering controls					
	Substance/mixture related measur prevent exposure during identified		In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.			
	Structural measures to prevent exposure:		In accordance with Section 7.			
	Organisational measures to prevenexposure:	nt	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent exp	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.			
	The state of the providing of the provid		Use non-sparkling ventilation system.			
		Provide appropriate personal protective equipme 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			



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Trading name:		GRAM DECOLORIZER SOLUTION 2						
Product code:	GD2-OT-X**	Revision date:	23 Dec 2022	Version:	5			

.1	Information on basic physical and	:hemical properties			
		Value	Method		
	Physical state:	liquid	No information available		
	Colour:	colourless	No information available		
	Odour/odour threshold:	acetone like/no information available	No information available		
	Melting point / freezing point:	No information available	No information available		
	Boiling point or initial boiling point and boiling range:	No information available	No information available		
	Flammability:	No information available	No information available		
	Lover and upper explosion limit:	No information available	No information available		
	Flash point:	20 °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		

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.			



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

amended by Regulation (EU) No. 2020/878

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Trading name:	GRAM DECOLORIZER SOLUTION 2					
Product code:	GD2-OT-X**	Revision date:	23 Dec 2022	Version:	5	

	oxicological inforration on hazard cla		in Regulati	ion (FC) No 127	72/2008	
Acute t		oses us definica i	Tregular.	1011 (20) 140 127	2,2000	
Route of exposure:	Method	Species		LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure t	ime Results
Oral:	-	rat		LD <sub>50</sub>	-	7.060 mg/kg (ethanol) 5.800 mg/kg (acetone)
Dermal:	-	rabbit		LD <sub>50</sub>	-	>20.000 mg/l (ethanol) 20.000 mg/kg (acetone)
Inhalation:	-	rat		LC <sub>50</sub>	4 h	>8.000 mg/l (ethanol) 76 mg/l (acetone)
Spacific	target organ toxic	ity single over	ocura (STO	T CEV		
Specific		ecific effects	isule (310	Target o	organ	Note
Oral:	No information		N	No information available		-
Dermal:	No information			No information available		-
Inhalation:	Narcotic effec	ts	N	o information a	May cause drowsiness or dizziness.	
Aspirat	ion hazard:	N	o informa	tion available.		
: '		:				
Irritatio	n and corrosion					
	Exposi	ure time	Species	Evaluati	on Method	Note
Skin corrosion/irritat	ion:	-		-	-	-
Serious eye damage/irritatio	on -	-		-	-	-
Sensitiz	zation					
Skin sensitizatio	1	nformation avail	able.			
		nformation avail				



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Trading name:		GRAM DECOLORIZER SOLUTION 2					
Product code:	GD2-OT-X**	Revision date:	23 Dec 2022	Version:	5		

Oral exposure:	unconscious	of great q ness and alcoh	uantities may ol poisoning. In	cause dizzin case of swallowi		nausea and
Dermal exposure:  After prolonged or repeated exposure symptoms may include: de cracking of skin.						dryness and
Inhalation expos	ure: Inhalation of membranes.	great quantitie	es may cause diz	ziness, euphoria	and mild irritation	of the mucou
Eye exposure:	May cause ir	ritation and re	dness.			
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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	Specific target	organ toxicity – repeated e	xpos	ure (STOT	RE):		
		Specific effec	cts		Target organ	Note	
Subacu	te oral	No information available			No information available	-	
Subacute dermal No infor		No information available			No information available	-	
Subacute inhalation No information		No information available			No information available	-	
Subchr	onic oral	No information available			No information available	-	
Subchr	onic dermal	No information available			No information available	-	
Subchr	onic inhalation	No information available			No information available	_	
Chronic	oral	No information available			No information available	-	
Chronic	dermal	No information available			No information available	_	
Chronic	inhalation	No information available			No information available	-	
		arcinogenicity; mutagenicit					
	CMR effects (c	arcinogenicity; mutagenicit	y; rep	roductive	toxicity)		
	Carcinogenicit		Based on available data, the classification criteria are not met.				
	Mutagenicity i	n vitro:	Based on available data, the classification criteria are not met.				
	Genotoxicity:	•	Based on available data, the classification criteria are not met.  Based on available data, the classification criteria are not met.				
	Mutagenicity i						
	Germ cell muta	-	Based on available data, the classification criteria are not met.				
	Reproductive t	coxicity:	Base	ed on avail	able data, the classification c	riteria are not met.	
	Summary of properties:	evaluation of the CN	ИR	Based on met.	available data, the classifica	ation criteria are no	
11.2	Information or	n other hazards:					
11.2.1.	Endocrine disr	upting properties:					
	components c disrupting pro Article 57(f) regulation (EU	e/mixture does not contained to have endocrible perties according to REAL or Commission Delegat D) 2017/2100 or Commission Delegat D) 2018/605 at levels of 0.1%	ine CH ed on				

#### **SECTION 12. Ecological information**



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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) 6.210 mg/l (acetone)	-
Crustacea:	EC <sub>50</sub>	48 hours	daphnia magna	No information available	7.800 mg/l (ethanol) 8.800 mg/l (acetone)	-
Algae/aquatic plants	IC <sub>50</sub>	4 days	algae	No information available	5.000 mg/l / 7d (ethanol) 530 mg/l (acetone)	-
Other organisms	-	-	-	-	-	-
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	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2	Persiste	ence and degradability			
	Abiotic	degradation			
		Degradation half-lives	Method	Evaluation	Note
Marine w	vater	No information available	No information available	No information available	-
Fresh wa	ter	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	-



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	Biodegr	adati	on									
% De	gradation	n	Time (	days)		Μ	lethod		Evaluation	า		Note
No info availabl	rmation		No ir available	formatio		lo info	ormation le		informatior ilable	1	No info	ormation
avanabi			avanabic		u,	vanab		uvu	ilabic		avanab	
12.3	Bioaccu	mula	tive potentia	al								
	Octanol	-wate	er partition o	oefficier	nt (log	Kow)			:			
Va	lue	Con	centration	рН	°C	5	Method		Evalua	ation		Note
-		-		-	-	-	•		-		-	
	Riocono	antra	tion factor (	BCE)								
V	alue	.emia	Speci		0 0 0 0 0 0 0 0 0	N	 Лethod		Evaluatio	on		Note
		N		formatio	n No		rmation	No	o informatio			
-		а	vailable			/ailabl			ailable		-	
					0 0 0 0 0 0 0 0 0 0 0 0 0 0 0							
	CI .											
	Chronic	ecot	oxicity		•							
	Value		Dos	se t	xposu time		Species		Method	Evalu	uation	Note
				No			No	No		No		
Chronic	toxicity	on fis	h LC <sub>50</sub>		ormat ailable		information available		formation ailable	inform availab		-
				No		_	No	No		No		
	toxicity on a ( <i>Daphi</i>		EC <sub>50</sub>		ormat		information	1	formation	inform		_
	F			av	ailable	9	available	av	ailable	availab	ole	
12.4	Mobility	in s	ail									
1 L,-T				ibution i	n envi	ironm	ental compar	tmer	nts:			
		···········	on available			. •	z.nai compai					
	Surface											
	Valu	ie	°C		Conc	entra	tion	M	lethod			Note



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		No No information available available		No information available	No informatio available	on -	
	A .l						
Transpo		A/I	desorption  D coefficient  ry's constant	log Kow	Evaporation rate	Method	Note
Soil-wa	ter	No availa	information able	No information available	No information available	No information available	-
Water-a	air	No availa	information able	No information available	No information available	No information available	-
Soil-air		No availa	information able	No information available	No information available	No information available	-
12.5	This sub	ostance	and vPvB asset e/mixture conta very persistent	ins no component	s considered to be nulative (vPvB) at l	either persistent, evels of 0.1% or hi	bioaccumulative and gher.
	This subtoxic (Pl  Endocri  The subtoxic according	ne disi	e/mixture conta very persistent rupting propert e/mixture does i REACH Article 5	ins no component and very bioaccur ies not contain compo	nulative (vPvB) at longer onents considered on Delegated regula	evels of 0.1% or hi	gher.  disrupting propertie
12.6.	This subtoxic (Pl  Endocri  The subtoxic according	ne disi estance ostance ng to F	e/mixture conta very persistent rupting propert e/mixture does of REACH Article 5 J) 2018/605 at l	ins no component and very bioaccur es not contain compo 7(f) or Commission	nulative (vPvB) at longer onents considered on Delegated regula	evels of 0.1% or hi	gher.  disrupting propertie
12.6.	This sub toxic (Pl Endocri The sub accordin Regulat	ne disi estance ng to F ion (El	e/mixture conta very persistent rupting propert e/mixture does REACH Article 5 J) 2018/605 at I	ins no component and very bioaccur les not contain compo 7(f) or Commission evels of 0.1% or hi	nulative (vPvB) at longer onents considered on Delegated regula	to have endocrine	disrupting propertie:
12.6.	This subtoxic (Pi Endocri The sub accordin Regulat Other a	ne dispostance ne dispostance ng to F ion (El dverse	e/mixture conta very persistent rupting propert e/mixture does REACH Article 5 J) 2018/605 at I	ins no component and very bioaccur  ies  not contain compo 7(f) or Commission evels of 0.1% or hi	onents considered on Delegated regula	to have endocrine	gher.  disrupting properties
12.6. 12.7.	This subtoxic (Pi  Endocri  The subtoxic according Regulation Contents of the	ne dispostance ne dis	e/mixture conta very persistent rupting propert e/mixture does of REACH Article 5 J) 2018/605 at l effects product or its r	ins no component and very bioaccur  ies  not contain compo 7(f) or Commission evels of 0.1% or hi	onents considered on Delegated regula	to have endocrine	gher.  disrupting properties
12.6. 12.7. <b>SECTIO</b> 13.1	This subtoxic (Pl  Endocri  The subtoxic according Regulation Control	ne dispostance of the dispostanc	e/mixture contavery persistent rupting propert e/mixture does of REACH Article 5 J) 2018/605 at l effects product or its r	ins no component and very bioaccur  les not contain component component contain component contain component contain component component contain contai	onents considered on Delegated regula	to have endocrine	gher.  disrupting properties
12.6. 12.7. <b>SECTIO</b> 13.1	This subtoxic (Pi  Endocri The subtoxic according Regulation Continuation Continuat	ne disposation (EU disposation) disposation (	e/mixture contavery persistent rupting propert e/mixture does in REACH Article 5 J) 2018/605 at I  effects product or its r  consideration ment methods	ins no component and very bioaccur  ies  not contain component component contain component contain component contain component component contain conta	onents considered on Delegated regula	to have endocrine tion (EU) 2017/210	disrupting propertie
12.5 12.6. 12.7. <b>SECTIO</b> 13.1. 13.1.1.	This subtoxic (Pl  Endocri The subtoxic according Regulate  Other at Do not  Waste  Produ Subm Protee	ne dispostance ne dis	e/mixture contavery persistent rupting propert e/mixture does of REACH Article 5 J) 2018/605 at I  effects product or its re consideration ment methods kaging disposa	ins no component and very bioaccur  ies  not contain component component contain component contain component contain component component contain conta	onents considered on Delegated regularing gher.  er system, waterwarized by the Minist	to have endocrine tion (EU) 2017/210	disrupting propertie



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13.1.3.						
	No information available					
13.1.4.	Sewage disposal – relevant information:					
	Waste must not be dispos	ed of into the sewage system.				
	· · · · · · · · · · · · · · · · · · ·					
13.1.5.	Other disposal recommen					
	authorized by the ministry	oduct's remains into the sewage system. Submit the remains to the collectors in charge. Do not dispose of the packaging into the sewage system. Submit ectors authorized by the ministry in charge. Unused product residues may be				
13.1.6.	Relevant Community prov	isions:				
	Disposal must be made ac	cording to official regulations.				
SECTION	N 14 TRANSPORT INFORM	ATION				
	Transporting/shipment by re	oad (ADR)				
UN num	ber:	1170				
UN prop	er shipping name:	Ethanol solution				
Transpor	t hazard class(es):	3				
Packing	group:	II .				
Environn	nentally hazardous:	-				
Special p	precautions for user:	-				
	Transporting/shipment by ra	ail (RID)				
UN num	ber:	1170				
UN prop	er shipping name:	Ethanol solution				
Transpor	t hazard class(es):	3				
Packing	group:	II .				
Environn	nentally hazardous:	-				
Special p	precautions for user:	-				
	Inland waterway transport (A	ADN)				
UN num	ber:	1170				
	er shipping name:	Ethanol solution				
Transpor	t hazard class(es):	3				
Packing	group:	II .				
Environn	nentally hazardous:	-				
Special p	precautions for user:	-				



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

SECTIO	CTION 15. Regulatory information				
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorization and/or res	strictions of use			
	Authorizations:	-			
	Restrictions:	-			



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15.2 Chemical safety assessmen	nt
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
Information according 199 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	(REACH).  REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);
	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
	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;
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;

SECTION 16. Other information		
16.1 Indication of changes:	-	



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16.2	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.		cation and procedure (	used to derive the classification for mixture according to Regulation (EC)		
Classifi	Classification		Classification procedure		
-			-		
16.5.	Releva	nt H statements (numb	er and full text)		
		225	Highly flammable liquid and vapor.		
	H:	319	Causes serious eye irritation.		
		336	May cause drowsiness or dizziness.		
		(EUH066)	Repeated exposure may cause skin dryness or cracking.		
16.6.	Trainin	g advice:	-		
16.7.			** "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	
-	



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SECTI	ON 1: Identification of	the substance	e/mixture	and of the company/undertaking	
1.1	Product identifier				
	Trading name:	GRAM SAFF	RANIN SO	LUTION	
	Chemical name:	-			
	Catalogue number:	GSF-OT-X**	GSF-OT-X**		
1.2	Relevant identified us	es of the subst	tance or m	nixture and uses advised against	
	Uses:		For use	in Gram staining using BioGram 4 kit.	
	Uses advised against:		Only the	e identified uses are advised.	
Reason why uses		sed against: device,		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:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent p	person:	msds@biognost.hr		
	National contact:		-		
1.4	Emergency telephone	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	Classification according to Regulation (EC) No 1272/2008 (CLP)					
	Hazard class and ca	tegory code:	Hazard statements*:			
	Flam. Liq. 3		H226			
2.1.2.	Additional information					
	-					
*For fu	Ill text of Hazard- and EU Haza	ard-statements: see S	ECTION 16			
2.2	Label elements					
	Product identification: GRAM SAFRANIN SOLUTION					
	Identification number:	mber: -				
	Authorization number:	-				



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	Hazard pictograms:	GHS02			
	Signal word:	Danger			
	Hazard statements:	H226 Flammable liquid and vapor.			
	Precautionary statements:	P210 Keep away from heat, hot sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.			
	Supplemetal hazard information (EU):	-			
2.3	Other hazards				
	The product has no other know	n specific hazards for human or environment.			
	Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.				
	Endocrine disrupting property:	Based on available data, does not contain endocrine disruptors.			

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

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



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	Following eye contact:	In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 10 minutes). If the symptoms remain, immediately call in ophthalmologist.	
	Following ingestion:	Place the victim in a comfortable position. Rinse the mouth with clean water. If the victim is conscious induce vomiting.  Do not give the victim anything orally, and do not induce vomiting if	
		the victim is unconscious or suffers from convulsions.	
	Self-protection of the first aider:	-	
4.2	Most important symptoms and effects, both acute and delayed		
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.	
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.	
	Following eye contact:	May irritate the eyes.	
	F 11 ' ' '	Industion of larger quantities may affect the central nervous system	
	Following ingestion:	Ingestion of larger quantities may affect the central nervous system.	
4.3		cal attention and special treatment needed	

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 self-contained breathing apparatus. Cool the fire affected containers wi water spray. Use water spray to dissipate alcohol vapours.		
5.4	Additional information		
	-		



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

SECTIO	ON 7. Handling and storage
7.1	Precautions for safe handling
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. Th	oroughly wa	sh hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities			
	Technical measures and storage conditions:	away from unopened	well-ventilated place, protected from sunlight, a sources of heat and ignition, in its original, and hermetically sealed packaging, away dizing agents, food, feed and articles of ion.	
	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:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain the directly leads into sewage system. Secure proper ventilation.		
	Further information on storage conditions:	and do n	ace the unused material in the storage room not use empty containers for storing other. Do not store with incompatible materials (see 0).	
7.3	Specific end use(s)			
	Recommendations:	_		
	Industrial sector specific solutions:	-		

SECTION 8. Exposure controls/personal protection					
8.1 Control parameters					
Substance	CAS No	· ·	exposure limit t term values	Biological limit values	
		ppm	mg/m³	-	
Ethanol	64-17-5	1000/-	1900/-	-	
			·		
Substance name: -					



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r roudet code.	031-01-X	revisie	Jii date.	23 Dec 2022	version. 0		
				T			
EC No:	- CAS No	• -					
DNEL							
		Inc	dustrial				
Route of	Acute	Acute		Chronic	Chronic		
exposure:	effect local	effect systemic	С	effect local	effect systemic		
Oral	-	-	-		-		
Inhalation	1900 mg/m <sup>3</sup> (ethanol)	-	-		380 mg/m³ (ethanol)		
Dermal	-	-	-		343 mg/kg (ethanol)		
Critical physical p	arameters: solubility,	flammability, cor	rosivity:	-			
		Co	nsumer				
Route of	Acute	Acute		Chronic	Chronic		
exposure:	effect local	effect systemi	С	effect local	effect systemic		
Oral	-	-	-		87 mg/kg bw/day (ethanol)		
Inhalation	950 mg/m³ (ethanol)	-	-		114 mg/m³ (ethanol)		
Dermal	-	-	-		206 mg/kg (ethanol)		
PNEC			- 1				
Environmental pro	otection target		PNEC				
Fresh water			0.96 mg/l (ethanol)				
Freshwater sedim	ents		3.6 mg/kg (ethanol)				
Marine water			0.79 mg/l (ethanol)				
Marine sediments			2.9 mg/kg (ethanol)				
Food chain			380-720 mg/kg (ethanol)				
Microorganisms i	n sewage treatment		580 mg/l (ethanol)				
Soil (agricultural)			0.63 mg/kg (ethanol)				
Air			no information available				
8.2 Expo	sure controls						
8.2.1. Appr	opriate engineering	controls					
Substance/mixture related measures to prevent exposure during identified uses:			In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.				
Struc expo	tural measures to prosure:	event	In accordance with Section 7.				



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	Organisational measures to prever exposure:	nt	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent exp	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.		
	recinited measures to prevent exposure.		Use non-sparkling ventilation system.		
			Provide appropriate personal protective equipment, safety shower and eye-wash station.		
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield ISO 16321-1:2022, EN 166).			
8.2.2.2.	Skin protection				
	Hand protection:	Use appropriate, chemical-resistant protective gloves (EN 374)			
	Other skin protection:	Use ap	propriate protective clothing.		
8.2.2.3.	Respiratory protection:	concer in the contac	e of normal usage and ventilation, it is not necessary. If ntration of ethyl alcohol exceeds occupational exposure limits air, use a self-contained breathing apparatus. For short t and if the oxygen content of the air is greater than 18 %, use ective gas mask with filter A (EN 14837/A1).		
8.2.2.4.	Thermal hazards:	No the	ermal 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 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		

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



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	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:	49 °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
9.2	Other information		
	-		

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

SECTION 11. Toxicological information										
11.1 Inform	Information on hazard classes as defined in Regulation (EC) No 1272/2008									
Acute	Acute toxicity:									
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results					
Oral:	-	rat (ethanol)	LD <sub>50</sub>	_	7.060 mg/kg					
Dermal:	-	rabbit (ethanol)	LD <sub>50</sub>	_	>20.000 mg/l					



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Inhalation:		-	rat (ethanol)		LC <sub>50</sub>		4 h	>	>8.000 m	ng/l
Specific	c targe	t organ toxicit	y – single expo	osure (S	TOT SE):					
, - I			ific effects			Target orga	n	<u> </u>	Note	
Oral:	١	lo information			No info	rmation avail				
Dermal:	٨	lo information	available		No info	rmation avail	able -	•		
Inhalation:	١	lo information	available		No info	rmation avail	able -			
Aspirat	ion ha	zard:	N	lo infori	mation av	vailable.				
<u> </u>			<u> </u>							
Irritatio	n and	corrosion								
		Exposur	e time	Spec	ies	Evaluation	Method		Note	
Skin corrosion/irritat	ion:	-	-			-	-	-		
Serious eye damage/irritatio	on	-	-			-	-	-		
Sensitiz			• .• •							
Skin sensitizatio			ormation avai							
Respiratory sens	sitizatio	on: No Int	ormation avai	labie.						
Sympto	oms re	lated to the pl	nysical, chemic	al and t	oxicoloa	ical character	istics			
Oral exposure:		Absorption unconscious	of great conness and alcohy y occur. Repea	quantitie nol poise	es may oning. In o	cause dizz	ziness, drun wing great q		nausea a	
Dermal exposur	e:	After prolon cracking of s	ged or repea kin.	ited exp	oosure s	ymptoms ma	ay include: d	lefatting,	dryness	and
Inhalation expo	sure:	Inhalation of membranes.	great quantiti	es may o	cause diz	ziness, eupho	ria and mild i	rritation o	of the mu	ıcous
Eye exposure:		May cause ir	ritation and re	dness.						
Repeat	ed dos	se toxicity (sub	acute, subchro	onic, ch	ronic)	1			i	
		Dose	Exposure time	Speci	es	Method	Evaluatio	on	Note	
Subacute oral	No avai	information lable	No information available	No inforr availa	nation ble	No information available	No infor available		_	



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Subacute dermal	No i availa	information ble	No information available	No information available	No information available	No inform available	nation	-
Subacute inhalation	No i availa	information ble	No information available	No information available	No information available	No inform available	nation	-
Subchronic oral	No i availa	information ble	No information available	No information available	No information available	No inform available	nation	-
Subchronic dermal	No i availa	information ble	No information available	No information available	No information available	No inform available	nation	-
Subchronic inhalation	No i availa	information ble	No information available	No information available	No information available	No inform available	nation	-
Chronic oral	No i availa	information ble	No information available	No information available	No information available	No inform available	No information available	
Chronic dermal	No i availa	information ble	No information available	No information available	No information available	No information available		-
Chronic inhalation	No i availa	information ble	No information available	No information available	No information available	No inform available	nation	-
Specific	target	organ toxicit	·	xposure (STOT				
			Specific effec	ts	Target o			Note
Subacute oral	I		tion available		No information		-	
Subacute derma Subacute inhalat			tion available		No information		-	
Subacute Innaiat Subchronic oral	.1011		tion available		No information		-	
Subchronic derm	nal		tion available		No information available -  No information available -			
Subchronic inhal			tion available		No information		_	
Chronic oral			tion available		No information		_	
			tion available				_	
	n		tion available				_	
Chronic dermal Chronic inhalatio		No informa	tion available tion available	/; reproductive	No inform	natio	nation available nation available	nation available -
	(		,,	,,				



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	Mutagenicity in vitro:	Bas	sed on available data, the classification criteria are not met.
	Genotoxicity:	Bas	sed on available data, the classification criteria are not met.
	Mutagenicity in vivo:	Bas	sed on available data, the classification criteria are not met.
	Germ cell mutagenicity:	Bas	sed on available data, the classification criteria are not met.
	Reproductive toxicity:	Bas	sed on available data, the classification criteria are not met.
	Summary of evaluation of the CN properties:	ЛR	Based on available data, the classification criteria are not met.
11.2	Information on other hazards:		
11.2.1.	Endocrine disrupting properties:		
	Based on available data, does not conta endocrine disruptors.	ain	
11.2.2.	Other informations:		
	-		

SECTION 12. Ecologi	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	
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	-	



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Tradir	ng name	:				GRAM SAFRA	λN	IN SOLUTIO	N	ruge 12		
Produ	ıct code:	: G	SF-OT-X**		F	Revision date:		23 Dec 202	22	Versi	on:	6
Algae/aquatic plants		olants	IC <sub>50</sub>	72 hours		No information		No information available		rmation e	-	
Other	organism	าร	-	-		_	-		-		-	
12.2			nd degradal	oility								
	Abioti		dation									
		De	gradation h	alf-lives		Method		Evaluation		N	ote	
Marine	e water	No ir	nformation a	vailable		information ailable		o informatior vailable	-	-		
Fresh	water	No ir	nformation a	available		information ailable		o informatior vailable	۱ -	-		
Air		No ir	nformation a	available	No information available		No information available		1 -	-		
Soil		No ir	nformation a	available		No information available		No information available				
	D. 1											
0/ D	<u></u>	gradatio		1 \				- I .:				
	egradatio		Time (	•	Method		Evaluation  No information				ote	
availak	ormation ole		No in available	information		No information available		available		No informa available	ition	
12.3	Bioacc	umulat	tive potentia	ıl								
	Octano	ol-wate	er partition o	oefficient (	log l	Kow)						
V	alue	Con	centration	рН	°C	Method		Evalua	ation		Note	
-		-			-	-		-		-		
	Biocor	centra	tion factor (	B(F)								
,	Value		Speci			Method		Evaluatio	on	N	lote	
-	. 4.40	N av		formation		No information available		No information available		-		
		a	variable		avc			avanable				



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	Chroni	c ecoto	xicity							
Value Do		Dose	Exposure time		Species Method		od Evaluation		Note	
Chroni	c toxicity	on fish	LC <sub>50</sub>	No information available	No inforr availa	mation i	No nformati available		ormation ilable	-
	c toxicity cea ( <i>Daph</i>		EC <sub>50</sub>	No information available	No inforr availa	mation i	No nformati available		ormation ilable	-
12.4	Mobilit	y in soi	il							
12.4			dicted distributi	on in environm	ental c	ompartm	ents:			
		······································	n available	OIT III CIIVIIOIIIII	CIIIAIC	.ompartin	CIILO.			
	Surface									
	Val		°C	Concentra	tion		Method			Note
	No No information infor			No information available		No information available		-		
Transp		A/I	desorption  D coefficient	log Kow	Ev	vaporation	n rate	Meth	nod	Note
Soil-wa	ater	No availa	information	No information available		n No information available		No information available		-
Water-	air	No availa	information	No information available				No information available		-
Soil-air No information available		No information				lo inforn vailable	nformation _ able			
12.5	Results	of PBT	and vPvB asses	ssment						
			lable data, the p		t cont	ain any PE	BT or vPv	B substa	nces.	
	1									
12.6.	Endocr	ine disi	rupting properti	ies						
	Pacad	an avai	lable data door	not contain en	docrin	o dicrupto	orc			



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12.7.	Other adverse effects			
	Do not let the product or it	s residues reach sewer system, waterways and soil.		
·				
SECTIO	N 13. Disposal consideration	ons		
13.1	Waste treatment methods			
13.1.1.	Product/Packaging dispo	sal:		
	Submit for disposal to the Protection.	e legal person authorized by the Ministry of Environmental and Nature		
13.1.2.	Waste codes/waste desig	nations according to Law:		
	Packaging that contains r	esidual hazardous substances or is contaminated with hazardous substances		
13.1.3.	Waste treatment – releva	nt information:		
	No information available			
13.1.4.	Sewage disposal – releva	nt information:		
	Waste must not be dispo	sed of into the sewage system.		
	1			
13.1.5.	Other disposal recommer			
	authorized by the ministr	oduct's remains into the sewage system. Submit the remains to the collectors y in charge. Do not dispose of the packaging into the sewage system. Submit ectors authorized by the ministry in charge. Unused product residues may be		
13.1.6.	Relevant Community pro	visions:		
	Disposal must be made a	ccording to official regulations.		
	•			
SECTIO	N 14 TRANSPORT INFORM	IATION		
	Transporting/shipment by	road (ADR)		
UN num	nber:	1170		
UN proper shipping name:		Ethanol solution		
Transpo	rt hazard class(es):	3		
Packing	group:	III		
Environi	mentally hazardous:	-		
Special	precautions for user:	-		
	Transporting/shipment by	rail (RID)		
UN num	nber:	1170		



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UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport	(ADN)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by	sea (IMDG)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	lii .
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Anof MARPOL 73/78 and the IBC code	<b>-</b>
Transporting/shipment by	air (ICAO-TI/IATA-DGR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Further information: volume in IATA: Sp	ecial Provision 144 – An aqueous solution containing 24% or less alcohol by is not subject to classification. ecial Provision A58 - An aqueous solution containing 24% or less alcohol by is not subject to classification.

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

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



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

SECTION 16. Other information	
16.1 Indication of changes:	-



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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 (num	ber and full text)			
	H: 225	Highly flammable liquid and vapor.			
	226	Flammable liquid and vapor.			
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
-