



Page 1 of 17

Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION				
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4

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

SECTIO	ON 2. Hazards identification					
2.1	Classification of the substar	nce or mixture				
2.1.1	Classification according to I	Regulation (EC) No	> 1272/2008 (CLP)			
	Hazard class and ca	tegory code:	Hazard statements*:			
	Flam. Liq. 3		H226			
	Aquatic Chronic 3		H412			
2.1.2.	Additional information					
	-					
*For fu	Ill text of Hazard- and EU Haza	ard-statements: se	e SECTION 16			
2.2	Label elements					
	Product identification:	GRAM CRYS	TAL VIOLET 1% SOLUTION			
	Identification number:	-				
	Authorization number:	-				



Page 2 of 17

Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION				
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4

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

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-xxxx	<10 %	ethanol	Flam. Liq. 2; H225		
548-62-9/ 208-953-6/ 612-204-00-2	-	≤1 %	[4-[4,4'- bis(dimethylamino)benzhydrylidene] cyclohexa-2,5-dien-1- ylidene]dimethylammonium chloride	Acute Tox. 4; H302 Eye Dam. 1; H318 Carc. 2; H351 Aquatic Acute 1; H400 Aquatic Chronic 1; H410		
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		

SECTIO	N 4. First aid measures
4.1	Description of first aid measures



Page 3 of 17

Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION				
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4

	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 eff	ects, 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.
4.3	Indication of any immediate media	cal attention and special treatment needed
	-	

SECTIC	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Water, foam, dry powder, CO ₂			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the substance or mixture				
	Hazardous combustion products:	Mixture with combustible ingredients. Forms explosive mixtures with air at elevated temperatures. Development of hazardous combustion gases or vapours possible in the event of fire. Vapours are heavier than air and may spread along floors.			
5.3	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.				
5.4	Additional information				

BIOGNOST®

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

Page 4 of 17

Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION				
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4

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 measu	ires		
6.1	Personal precautions, protective equipment and emergency procedures			
6.1.1.	For non-emergency personnel			
	Protective equipment:	Use personal protective equipment (see Section 8).		
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.		
	Emergency procedures:	Mark the area using proper signs.		
6.1.2.	For emergency responders:			
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).			
6.2	Environmental precautions:			
	Do not let product enter drains	s. Risk of explosion.		
6.3	Methods and material for cont	ainment and cleaning up		
6.3.1.	Bunding, covering of drains; capping procedures:	Cover drains. Collect, bind, and pump off spills.		
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.		
6.3.3.	()ther information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).		
6.4	Reference to other sections			
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.			

SECTIO	SECTION 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge. Do not smoke.			



Page 5 of 17

Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION					
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4	

	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	noroughly was	sh hands after work and before eating.		
7.2	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:	well ventil	ghtly closed and upright set containers in a ated storage rooms at temperatures ranging 25 °C. Protect from heat and direct sunlight.		
	Packaging materials:		Manufacturer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.			
	Advices for storage equipment:	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:	and do no	ace the unused material in the storage room ot 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 par	ameters						
Substance		CAS No		Occupational exposure limit values/short term values		Biological limit values		
				ppm	mg/m ³			
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		
Substar	ice name:	-						
EC No:		-	CAS No:	-				
DNEL	DNEL							
					Industrial			



Trading name	:	GRAM C	RYSTAL VIOLET	1% SOLUTIO	N	
Product code	GC1-OT-X**	Date o	of compilation:	11 June 20	19 Version:	4
Route of exposure:	Acute effect local	Acute effect systemi	Chro c effect		Chronic effect systemic	
Oral	-	-	-	-		
Inhalation	1900 mg/ m ³ (ethanol)	-	-		950 mg/m ³ (ethanol) 3 mg/ m ³ (phenol)	
Dermal	-	-	-	3	343 mg/kg (ethanol)	
Critical physica	parameters: solubili	ty, flammability, co	rrosivity: -			
		Co	onsumer			
Route of exposure:	Acute effect local	Acute effect systemi	Chro ic effect		Chronic effect systemic	
Oral	-	-	87		37 mg/kg (ethanol)	
Inhalation	950 mg/ m ³ (ethanol)	-			L14 mg/m ³ (ethanol)	
Dermal	-	-	-		206 mg/kg (ethanol) L23 mg/kg (phenol)	
PNEC	I	I				
Environmental	protection target		PNEC			
Fresh water			0.96 mg/l (ethan 0.0077 mg/l (phe			
Freshwater sed	iments		3.6 mg/kg (ethanol) 0.09125 mg/kg (phenol)			
Marine water			0.79 mg/l (ethanol) 0.00077 mg/l (phenol)			
Marine sedime	nts		0.00915 mg/kg (phenol)		
Food chain			no information a	-		
Microorganism	s in sewage treatmer	nt	2.1 mg/l (phenol)			
Soil (agricultur	51)		0.63 mg/kg (ethanol)			
	11 <i>)</i>		0.136 mg/kg (phenol)			
Air			no information a	vailable		
	posure controls					
8.2.1. Ap	propriate engineerin	ig controls				
	bstance/mixture rela event exposure durin		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	ructural measures to posure:	prevent	In accordance with Section 7.			



Page 7 of 17

Trading name:		1% SOLUTION			
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4

	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent ex	posure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.		
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	levels o	glasses that stick to face (EN 166) or visor in case of lower of concentration in air; protective gas mask that covers the face in case of higher levels of concentration in air.		
8.2.2.2.	Skin protection				
	Hand protection:	Regula Full co	otective gloves have to satisfy the specification of tion (EU) 2016/425 and the related standard EN 374. ntact: Glove material: butyl rubber Glove thickness: 0.70 mm Break through time: > 480 min contact: Gloves material: nitrile rubber Glove thickness: 0.40 mm Break through time: >120 min		
	Other skin protection:	footwe entire imperr	everyday work use cotton clothing (EN 340) and suitable ear, such as rubber boots (EN 20345) or shoes that cover the foot. In case of spilling hazard, use clothing made of neable material suitable for protection from liquid chemicals PVC, himex) and footwear made from the same material.		
8.2.2.3.	Respiratory protection:	with a	tive full face mask (EN 136) or half mask (EN 140) equipped filter for organic vapors, type "A" (boiling point >65°C) 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				
	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	ection 6		

SECTIO	IN 9. Physical and chemical properties
9.1	Information on basic physical and chemical properties



Page 8 of 17

Trading name:	(GRAM CRYSTAL VIOLET	1% SOLUTION		
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4

	Value	Method
Physical state:	liquid	No information available
Colour:	purple	No information available
Odour:	phenol like	No information available
Odor threshold:	No information available	No information available
pH:	No information available	No information available
Melting point / freezing point;	No information available	No information available
Initial boiling point and boiling range:	No information available	No information available
Flash point:	49°C	No information available
Evaporation rate:	No information available	No information available
Flammability (solid, gas):	No information available	No information available
Upper/lower flammability or explosive limits:	No information available	No information available
Vapour pressure:	No information available	No information available
Vapour density:	No information available	No information available
Relative density:	No information available	No information available
Bulk density:	No information available	No information available
Solubility(ies):	soluble (20°C)	No information available
Partition coefficient: n- octanol/water (log Kow):	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
Viscosity:	No information available	No information available
Explosive properties:	No information available	No information available
Oxidising properties:	No information available	No information available
Other information		

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



Page 9 of 17

Trading name:	GRAM CRYSTAL VIOLET 1% SOLUTION					
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4	

11.1 Information	n on toxicologica	l effects					
Acute toxic	city:						
Route of exposure:	Method	Species	Do LD ₅₀ /L ATE	C ₅₀ or	Exposure time		Results
Oral:	-	rat	LD	9 ₅₀	-		mg/kg (ethanol) g/kg (crystal violet)
Dermal:	-	rat	LD) ₅₀	_	660 mg	g/kg (phenol)
Inhalation:	-	rat	LC	•50	4 h	124.7 r	ng/l (ethanol)
Specific tar	get organ toxicit	y – single ex	(posure (STOT SI	E):		1
	Specific effects				Target organ		Note
Oral:	No information	lo information available			formation availab	le	-
Dermal:	No information	available		No in	No information available -		
Inhalation:	No information	available		No information available -			-
Aspiration	hazard:		No info	rmation	available.		
Irritation ar	nd corrosion						
	Exposure t	ime Spe	cies I	Evaluatio	on Method		Note
Skin corrosion/irritation:	Exposure t	ime Spe in vit study	ro _	Evaluatio	OFCD 431	cause	Note es burns (phenol)
	Exposure t	in vit	ro /	-			
corrosion/irritation: Serious eye damage/irritation	-	in vit study	ro /	-	OECD 431		es burns (phenol)
corrosion/irritation: Serious eye damage/irritation Sensitizatio		in vit study rabb	ro / it -	-	OECD 431		es burns (phenol)
corrosion/irritation: Serious eye damage/irritation Sensitization Skin sensitization:	- - on No inf	in vit study rabbi	ro / / - it - vailable.	-	OECD 431		es burns (phenol)
corrosion/irritation: Serious eye damage/irritation Sensitizatio	- - on No inf	in vit study rabb	ro / / - it - vailable.	-	OECD 431		es burns (phenol)
corrosion/irritation: Serious eye damage/irritation Sensitization Skin sensitization: Respiratory sensitiza	- - on No inf ation: No inf	in vit study rabbi ormation av	ro / / it - / ailable. /ailable.		OECD 431 OECD 405	corro	es burns (phenol)
corrosion/irritation: Serious eye damage/irritation Sensitization Skin sensitization: Respiratory sensitiza Symptoms	- on ation: No inf related to the pl	in vit study rabbi ormation av ormation av	ro / / it - /ailable. /ailable. nical and		OECD 431	corro	es burns (phenol)
corrosion/irritation: Serious eye damage/irritation Sensitization Skin sensitization: Respiratory sensitiza Symptoms Oral exposure:	on No infation: No informat	in vit study rabbi ormation av ormation av nysical, chen on available	ro / / it - / vailable. / vailable. / nical and		OECD 431 OECD 405	corro	es burns (phenol)
corrosion/irritation: Serious eye damage/irritation Skin sensitization: Respiratory sensitizat Oral exposure: Dermal exposure:		in vit study rabbi ormation av ormation av nysical, chen on available	ro / / it - /ailable. /ailable. /ailable.		OECD 431 OECD 405	corro	es burns (phenol)
corrosion/irritation: Serious eye damage/irritation Sensitization: Skin sensitization: Respiratory sensitization: Coral exposure:		in vit study rabbi ormation av ormation av nysical, chen on available on available	ro / it - railable. railable. nical and e. e.		OECD 431 OECD 405	corro	es burns (phenol)



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

GRAM CRYSTAL VIOLET 1% SOLUTION

Page 10 of 17

Trading name: Product code:

GC1-OT-X**

Date of compilation:

11 June 2019 Version:

4

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

Specific	target organ toxicit		•			
Culture 1		Specific effec	ts	Target o	-	Note
Subacute oral		tion available		No information		-
Subacute dermal Subacute inhalat		tion available		No information		_
Subacute innaiat		ition available		No information		_
Subchronic derm		ation available				_
Subchronic inhal		tion available		No information available No information available		_
Chronic oral		tion available		No information		_
Chronic dermal		tion available		No information		_



Page 11 of 17

Trading name:		GRAM CRYSTAL VIOLET	1% SOLUTION		
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4

Chron	ic inhalation	No information available)	No information available -			
	CN4D (()	,					
		(carcinogenicity; mutagenici	-				
	Carcinogenic	tity:	Bas	sed on available data, the classification criteria are not met.			
	Mutagenicity in vitro:			ed on available data, the classification criteria are not met.			
	Genotoxicity:			ed on available data, the classification criteria are not met.			
	Mutagenicity in vivo:			ed on available data, the classification criteria are not met.			
	Germ cell mutagenicity:			sed on available data, the classification criteria are not met.			
	Reproductive	e toxicity:	Bas	ed on available data, the classification criteria are not met.			
	Summary c properties:	of evaluation of the C	MR	Based on available data, the classification criteria are not met.			
11.2	Practical exp	eriences:					
	Classification	observations:		No information available			
	Other observ	ations:		No information available			
11.3	General note	·S:					
	-						

SECTION 12. E	SECTION 12. Ecological information									
12.1 Toxicity	/									
Acute (short- term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note				
Fish	LC ₅₀	96 hours	Leuciscus idus (Golden orfe; ethanol) S.gairdnerii (crystal violet) Oncorhynchus mykiss (rainbow trout; phenol)	-	-	8.140 mg/l (ethanol) 0.7 mg/l (crystal violet) 5.0 mg/l (phenol)				
Crustacea:	EC ₅₀	48 hours	Daphnia magna (Water flea)	-	-	9.268-14.221 mg/l (ethanol) 0.25 – 0.5 mg/l (crystal violet) 3.1 mg/l (phenol)				
Algae/aquatic plants	IC ₅₀	7 days	green algae	-	-	5.000 mg/l (ethanol) 0.42 mg/l (crystal violet) 61.1 mg/l (phenol)				



Page 12 of 17

Trading name:		GRAM CRYSTAL VIOLET	1% SOLUTION		
Product code:	GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4

Other organisms	-	-	-			_	-	-		
Chronic (long- term) toxicity	Do	se Expos		Sp	pecies	Method	Evaluatior	۱	Note	
Fish	LC ₅₀	96 ho	urs No	o informa	ation available	-	-	-		
Crustacea:	EC ₅₀	48 ho	urs No	No information available		-	-	-		
Algae/aquatic plants	IC ₅₀	72 ho	urs No	No information available		-	-	-		
Other organisms	-	-	-	-		-	-	-		
12.2 Persis	tence a	ind degrada	bility							
Abiot	ic degr	adation	-							
· · · ·	De	egradation h	nalf-lives		Method	Eval	uation		Note	
Marine water	No i	nformation	available	No ii avail	nformation able	No inforr available	nation	-		
Fresh water	No i	nformation	available	No ii avail	nformation able	No information available		-		
Air	No i	nformation	available	No ii avail	nformation able	No information available		-		
Soil	No i	nformation	available	No ii avail	nformation able	No information available		-		
Biode	gradati	on								
% Degradat	-	Time	(days)		Method Eva		Evaluation		Note	
94% (ethanol)		No ii available	nformatio	ⁿ OEC	D 301E	No inforr available	No information read		y biodegradable	
3.6% (crystal v	iolet)	28 days		OEC	D 301F	No information available		not re	adily biodegradable	
85% (phenol)		14 days		OEC	D 301C	No inforr available	nation	readil	y biodegradable	
12.3 Bioac	cumula	tive potenti	al							
		er partition		t (loa Kr	w)					
Value		centration	рН	°C	Method		Evaluation		Note	
-0,31 (ethanol)	-		-	-	experimental	_			pioaccumulation is not expected	
1.172 (crystal violet)	-		-	25℃	25°C OECD 107			k	bioaccumulation is not expected	



Page 13 of 17

												P	age 13 of 1	./
Trading	nam	e:				GRAM	I CRYS	STAL VI	OLET 1	% SOI	UTIO	N		
Product	t cod	e:	GC	1-OT-X**		Dat	te of co	ompilati	on:	11 Jur	ne 201	.9	Version:	4
1.47 (phe	enol)	-		-		30 °C	ECHA		-				paccumulatic t expected	on is
												no		
	Bioco	oncen	tratic	on factor (BC	F)									
Va	alue			Species			Metho	d	E	valuatio	on		Note	
No infor available		on	No avai	infor lable	mation	No in [.] availa	formati ble	on	No inf availat	ormatio ole	on	-		
-	Chro	nic eo	cotoxi	city	1		1		1		Ĩ			
	Valu	Je		Dose		oosure ime	Sp	ecies	Met	nod	Eva	luation	Not	e
Chronic toxicity on fish LC		LC ₅₀		No information available		mation able	No information available		No infor availa	mation able	-			
Chronic crustacea		-	')	EC ₅₀	No information available		No infor avail	mation able			No infor availa	mation able	-	
12.4	Mob	ility ir	n soil											
			•	cted distribu	tion in e	environ	mental	compart	ments:					
				available										
			nsion											
	No infor		n	°C No information	Nc	Concentratio No informatio available							Note	
	availa	able		available										
	۵طدم	rntio	n / de	esorption										
1				pefficient										
Transpor	rt			constant	lo	og Kow	E	vaporati	on rate		Metho	d	Note	
Soil-wate	Δr	No availa	able	information		No information No information available			nation No information available		tion	-		
Water-ai	ir	No availa	able	information	No ii availa	nformat able		lo inform vailable	nation	No ir availa	nforma able	tion	-	



Page 14 of 17

Page 14 of 17							/			
Trading	g name:		GRAM CF	RYSTAL VIOLET	1% SOLUTION					
Produc	ct code:	GC1-OT-X**	Date of	f compilation:	11 June 2019	Version:	4			
Soil-air	No availa	information able	No information available	No information available	No information available	-				
12.5	Doculto of	PBT and vPvB asse	comont							
12.5			ssment							
	Not applic	.abie.								
12.6	Other adv	erse effects								
	No furthe	r relevant informati	ion available.							
		osal consideratior	ıs							
13.1	Waste tr	reatment methods								
13.1.1.	Product	/Packaging disposa	al.							
13.1.1.		5 5 1		rized by the Minis	stry of Environmental	and Nature				
	Protectio	-		fized by the winte						
13.1.2.	Waste c	odes/waste designa	ations according to	o Law:						
	15 01 10 substan		contains residual h	azardous substand	ces or is contaminate	ed with hazardo	ous			
13.1.3.	Waste tr	reatment – relevant	t information:							
	No infor	mation available								
13.1.4.	Sewage	disposal – relevant	: information:							
		nust not be dispose		ge system.						
13.1.5.	Other di	sposal recommend	lations:							
	authoriz	•	in charge. Do not o	dispose of the pac	m. Submit the remain kaging into the sewa harge.					
13.1.6.	Relevant	t Community provi	sions:							
	Disposa	l must be made acc	cording to official r	egulations.						
SECTIO		ISPORT INFORMA								
SECHO		ng/shipment by ro								
UN nun		ng/sinpinent by 10	1170							



Page 15 of 17

Trading name: Product code: 6		G	RAM CRYSTAL VIOLET					
Product code:								
	GC1-OT-X**		Date of compilation:	11 June 2019	Version:	4		
		÷						
Transport hazard class	s(es):	3						
Packing group:		III						
Environmentally haza	rdous:	-						
Special precautions for	or user:	-						
Transporting	/shipment by rail (RI	[D)						
UN number:		117	0					
UN proper shipping n	ame:	Eth	anol solution					
Transport hazard class	s(es):	3						
Packing group:		III						
Environmentally haza	rdous:	-						
Special precautions for	or user:	-						
Inland water	way transport (ADN)							
UN number:		117	0					
UN proper shipping n	ame:	Ethanol solution						
Transport hazard class	s(es):	3						
Packing group:		III						
Environmentally haza	rdous:	-						
Special precautions fo	or user:	-						
Transporting	/shipment by sea (IN	/DG						
UN number:		117	0					
UN proper shipping n	ame:	Eth	anol solution					
Transport hazard class	s(es):	3						
Packing group:		III						
Environmentally haza	rdous:	-						
Special precautions fo	or user:	-						
Transport in bulk acc of MARPOL 73/78 and	0	-						
Transporting	/shipment by air (IC/	AO-1	I/IATA-DGR)					
UN number:		117	0					
UN proper shipping n	ame:	Ethanol solution						
Transport hazard class	s(es):	3						
Packing group:		ш						
Environmentally hazaı	rdous:	-						
Special precautions for	or user:	-						



Page 16 of 17

	GRAM CRYSTAL VIOLET	1% SOLUTION		
GC1-OT-X**	Date of compilation:	11 June 2019	Version:	4
	Duce of complication.		Version.	•
	GC1-OT-X**		GRAM CRYSTAL VIOLET 1% SOLUTIONGC1-OT-X**Date of compilation:11 June 2019	

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

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:	-
		EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);
	Other EU regulations:	EC Regulation No. 2037/200 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;
		EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;
		Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessme	ent
	None	

SECTION 16. Other information			
16.1	Indication of changes:	-	



Page 17 of 17

Page 1/ of					Fage 17 01 1	.7				
Tradin	ig nar	me:			G	RAM CRY	STAL VIOLE	T 1% SOLUTION		
Produ	ct coo	de:	GC1-OT-X**			Date of o	compilation:	11 June 2019	Version:	4
16.2	Abbreviations and acronyms:			rms:	PBT vPvB LD ₅₀ LC ₅₀ TCOJ	vBStrongly stable and strongly bioaccumulative. p_{50} Lethal dose, 50% p_{50} Lethal concentration, 50%				
16.3.		literat rce of	ure references a data:	and	Manu	ıfacturer's	MSDS file.			
16.4.		ssificati 2/2008	•	ure us	ed to d	lerive the c	lassification fo	r mixture according	to Regulation (E	C)
Classifi	catior	٦		С	lassifica	ation proce	edure			
_				-						
16.5.	Rele	evant H	l statements (n	umber	and fu	ıll text)				
	H:	H225 H226 H301 H302 H311 H314 H318 H314 H351 H351 H373 H400 H410 H412		Highly flammable liquid and vapor. Flammable liquid and vapor. Toxic if swallowed. Harmful if swallowed. Toxic in contact with skin. Causes severe skin burns and eye damage. Causes serious eye damage. Toxic if inhaled. Suspected of causing genetic defects. Suspected of causing cancer. May cause damage to organs through prolonged or repeated exposure. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. Harmful to aquatic life with long lasting effects.						
16.6.	Trai	ining a	dvice:	-						
16.7.	pr Further information: W in:				uct) re not	responsible for use or	e for conseque	erent volumes (differ ences in case of failur of the product descr	re to comply with	h

ANNEX: Exposure scenario resulting to chemical safety assessment

_



Page 1 of 15

Trading name:	G	GRAM LUGOL SOLUTION, STABILIZED				
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4		

SECTI	ON 1 IDENTIFICATION (OF THE SU	JBSTAN	CE/MI)	(TURE AND OF THE COMPANY/UNDERTAKING	
1.1.	Product identifier					
	Trading name:	GRAM L	UGOL SC	OLUTIO	N, STABILIZED	
	Chemical name:	-				
	Catalogue number:	GLS-OT-	-X**			
1.2.	Relevant identified use	s of the su	ubstance	or mix	ture and uses advised against	
	Uses:		For	use in	BioGram 4 Gram bacteria staining kit.	
	Uses advised against:		Onl	y the ic	lentified uses are advised.	
	Reason why uses advis	dvised against: The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Production Medical Devices and there is no reason to use it for other put			evice, registered at the Agency for Medicinal Products and	
1.3.	Details of the supplier	of the safe	ety data s	sheet		
	Supplier:		BioGnost Ltd.			
	Address:		Medjugorska 59, Zagreb			
	Telephone number:		+385 1 2409997			
	Fax no.:		+385 1 2404039			
	e-mail of competent p	erson:	msds@biognost.hr			
	National contact:		-			
1.4.	Emergency telephone	number				
	National Protection an	d Rescue l	Directora	ate:	112	
	Medical information:				+385 1 2348 342	
	Other information:				-	

SECTIO	TION 2 HAZARDS INFORMATION				
2.1.	Classification of the substance or mixture				
2.1.1.	Classification (REGULATION (EC)	No. 1272/2008	(CLP)		
	Hazard class and catego	ry code:	Hazard statements*:		
	Not identified as hazardous sub	Not identified as hazardous substance			
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazard-s	tatements: see S	ection 16		
2.2.	Classification according to EC D	irective Nr. 1272,	(2008 CLP)		
	Product identification:	GRAM LUGO	L SOLUTION, STABILIZED		
	Identification number:	-			
	Authorization no.: -				
	Hazard pictograms:	Hazard pictograms: -			
	Signal word:	-			

Page 2 of 15

Trading name:	GRAM LUGOL SOLUTION, STABILIZED				
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version:	4
					·

	Hazard statements:	-
	Precautionary statements:	-
	Further information:	-
2.3.	Other hazards	
	-	

SECTION 3 CC	ECTION 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)			
25655-41-8/ 607-771-8/ -	-	< 20	Polyvinylpyrrolidone- iodine	Not Classified			

SECTI	ION 4 FIRST AID MEASURES					
4.1.	Description of first aid mea	Description of first aid measures				
	General notes:		-			
	Following inhalation:		Carry the afflicted person out of the contaminated area into a well- ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to- mouth) and contact a physician.			
	Following skin contact:		Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact: Following ingestion:		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.			
4.2.	Most important symptoms	and eff	ects, both acute and delayed			
	Following inhalation:		ording to our findings, chemical, physical and toxicological properties of substance have not been entirely tested.			
	FOILOWING SKIN CONTACT.		cording to our findings, chemical, physical and toxicological properties of substance have not been entirely tested.			
	Following eye contact:		ording to our findings, chemical, physical and toxicological properties of substance have not been entirely tested.			
	Following ingestion:		ording to our findings, chemical, physical and toxicological properties of substance have not been entirely tested.			

SAFETY DATA SHEET

BIOGNOST[®] According to Regulation (EC) No. 1907/2006

Page 3 of 15

Trading name:	GRAM LUGOL SOLUTION, STABILIZED				
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4	

Indication of any immediate medical attention and special treatment needed 4.3. _

SECTI	ON 5 FIREFIGHTING MEASURES			
5.1.	Extinguishing media			
	Suitable extinguishing media:	Water spray, dry powder, CO_2 or alcohol-resistant foam		
	Unsuitable extinguishing media:	No information available		
5.2.	Special hazards arising from the su	ibstance 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.			

SECTIC	ON 6 ACCIDENTAL RELEASE M	IEASURES	
6.1.	Personal precautions, protective equipment and emergency procedures		
6.1.1.	For non-emergency personne	21	
	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 (s	see Section 8).	
6.2.	Environmental precautions:		
	Do not dispose of in sewage, Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National orate (NPRD) on 112.	
6.3.	Methods and material for cor	ntainment 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:	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.	
6.3.3.	Other information:	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.	

Page 4 of 15

Trading name:		GRAM LUGOL SOLUTIO	ON, STABILIZED	
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4

6.4.	Reference to other sections			
	See Section 7 for information on safe handling.			
	See Section 8 for information on personal protective equipment.			
	See Section 13 for disposal information.			

SECTIC	N 7 HANDLING AN STORAGE					
7.1.	Precautions for safe handling					
7.1.1.	Protection measures					
	Measures to prevent fire:		Keep away from sources of heat and ignition. Do not smoke.			
	Measures to prevent aerosol and dust generation	on:	Secure proper ventilation.			
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.			
	Other measures:		-			
7.1.2.	Advice on general occupational hygiene:					
	Do not eat, drink or smoke in the workspace. The	norou	ghly wash hands after work and before eating.			
7.2.	Conditions for safe storage, including any incor	npatik	pilities			
	Technical measures and storage conditions:	vent	o in tightly closed and upright set containers in a well ilated storage rooms, and away from sources of heat, ght, and other incompatible substances.			
	Packaging materials:	Man	ufacturer's original packaging.			
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.				
	Advices for storage equipment:	be re direc	storage must be made of hard material; floors must esistant to chemicals. There must be no drain that ctly leads into sewage system. Secure proper ilation.			
	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)					
	Recommendations:	-				
	Industrial sector specific solutions:	-				

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION						
8.1. Control parameters	3.1. Control parameters					
Substance	CAS No	Occupational exposure limit values/short term values	Biological limit values			



Page 5 of 15

Trading name:	GRAM LUGOL SOLUTION, STABILIZED								
Product code:	GLS-OT-X	**	Da	ate of	⁻ compila	ition:	11 Jur	ne 2019.	Version: 4
							2		
				p	pm	m	g/m³		
-		-			-		-	No inforr	mation available
Substance - name:									
EC No: -	C	CAS No:	-						
DNEL									
				Ind	ustrial				
Route of	Αςι	ute		Acute	;		Chron	ic	Chronic
exposure:	effect	local	effe	ct syst	emic		effect lo	ocal	effect systemic
Oral	-		-			-			-
Inhalation	-		-			-			-
Dermal	-		-			-			-
Critical physical par	ameters: sol	ubility, flar	nmability	y, corr	osivity:		-		
				Con	sumer				
Route of	Αςι	ute	Acute		Chronic		ic	Chronic	
exposure:	effect	local	effe	ct syst	emic	effect local		ocal	effect systemic
Oral	-		-			-			-
Inhalation	-		-			-			-
Dermal	-		-			-			-
PNEC									
Environmental prot	ection target	t			PNEC				
Fresh water					No infor	matior	n availabl	e	
Freshwater sedimer	nts				No infor	matior	n availabl	е	
Marine water					No infor	No information available			
Marine sediments					No infor	matior	n availabl	е	
Food chain					No information available				
Microorganisms in	sewage treat	tment			No information available				
Soil (agricultural)					No information available				
Air				No infor	matior	n availabl	е		
8.2. Exposu	ure controls								
8.2.1. Engine	ering measu	ires	8						
measu	Substance/mixture related measures to prevent exposure during identified uses: Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.								

Page 6 of 15

Trading name:	GRAM LUGOL SOLUTION, STABILIZED					
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4		

	Structural measures to pr exposure:	event	No information available		
	Organisational measures to prevent exposure:		Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to pr exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.		
8.2.2.	Personal protection equip	oment			
8.2.2.1.	Eye and face protection:		Safety glasses that stick to face (preventing splashing) (EN 166) or visor.		
8.2.2.2.	Skin protection				
			tive gloves must be according to the EU Directive 2016/425/EEC and ard 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 f	tive full face mask (EN 136) or half mask (EN 140) equipped with a or 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 related measures to prevent exposure: Structural measures to prevent exposure:		See Section 6		
			Use modern equipment.		
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.		
	Technical measures to prevent exposure:		See Section 6		

SECTI	SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES					
9.1.	Information on basic physical and chemical properties					
		Value	Method			
	Physical state:	liquid	No information available			
	Color:	yellow/amber	No information available			
	Odor:	neutral	No information available			
	Odor threshold:	No information available	No information available			
	pH:	No information available	No information available			
	Melting point / freezing point;	No information available	No information available			

Page 7 of 15

Trading name:	GRAM LUGOL SOLUTION, STABILIZED					
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version:	4	

	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapor pressure:	No information available	No information available
	Vapor density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	Soluble in water (20 °C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
.2.	Other information		

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:	High temperatures, ignition sources, open flame.		
10.5.	Incompatible materials:	Oxidants.		
10.6.	Hazardous decomposition products:	No information available.		

SECTION 11 TOXICOLOGICAL INFORMATION								
11.1. Information on toxicological effects								
Acute toxicity:								
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results			
Oral exposure:	No information available	-	LD ₅₀	-	-			



Page 8 of 15

Trading name:		CP	AM LUGOL SO				Page 8	0115
Product code:	GLS-OT-X**				11 June 2		Version:	4
Product code.	GLS-OT-X		ate of compil	ation.	II June 2	2019.	version.	4
Dermal exposure	No informatio	n -		LD ₅₀		-		-
Inhalation exposure:	No informatio available	on -		LC ₅₀		-		-
c			(0707.01					
Specific	target organ toxici						Not	
Oral exposure: No information avai					get organ	.1.1	Not	te
Oral exposure:					nation availa			
Dermal exposure		ation available			nation availa			
Inhalation exposi	ure: No inform	ation available	e No	o inform	nation availa	ible -		
Respirat	ory irritation:		No information	availab	le			
.								
Irritation	and corrosion Exposure	time 9	Species E	valuatio	n Metho	d	Note	
Skin irritation:	-	rab	-	, and a construction	-	-		
Eye irritation:	-	rab			_	-		
)								
Sensitiza	ation							
Dermal exposure	: No informatior	n available						
Inhalation exposure:	No information	ı available						
Sympton	ms related to the p	hysical chemi	cal and toxicol	naical ch	aracteristic	c		
Oral exposure:	According to	-	, chemical, phys	-			ties of the s	substance
Dermal exposure	. According to		, chemical, phys	sical and	l toxicologio	cal propert	ties of the s	substance
Inhalation exposi	Iro -	o our findings en entirely tes	, chemical, phys ted.	sical and	l toxicologio	cal propert	ties of the s	substance
Eye exposure:		o our findings en entirely tes	, chemical, phys ted.	sical and	l toxicologio	cal propert	ties of the s	substance
Ronasta	d dose toxicity (sub	acute subch	ronic chronic)					
hepeute	Dose	Exposure time	Species	Met	hod	Evaluatio	n Not	e
Subacute oral	No information available	No information available	No information available		rmation lable	No informatio available	on -	

Page 9 of 15

Trading name:	C	GRAM LUGOL SOLUTION, STABILIZED						
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4				

Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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

Page 10 of 15

Trading name:		GRAM LUGOL SOLUTION, STABILIZED					
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4			

	Genotoxicity:	No inf	ormation available				
	Mutagenicity in-vivo:	No inf	ormation available				
	Germ cell mutagenicity:	No inf	No information available				
	Reproductive toxicity:	No information available					
	Summary of evaluation of th	e CMR pro	perties: -				
11.2.	Practical experiences:						
	Remarks relevant for classified	cation:	No information available				
	Other remarks:		No information available				
11.3.	General notes:						
	-						

SECTION 12 ECOLOG	ICAL INFOR	RMATION:				
12.1. Toxicity						
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

Page 11 of 15

Trading name:	GRAM LUGOL SOLUTION, STABILIZED					
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4	4	

Ab	iotic d	ice and degrada legradation						
		Degradation ha	If-lives		Method		Evaluation	Note
Marine water	N	o information a	vailable	No info	ormation availab	le No inform	nation available	-
Fresh water	N	o information a	vailable	No info	ormation availab	le No inform	nation available	-
Air	N	o information av	vailable	No info	ormation availab	le No inform	nation available	-
Soil	N	o information a	vailable	No info	ormation availab	le No inform	nation available	-
Bic	degra	dation						
% Degrada	-	Time (day	/s)	N	/lethod	Evaluatio	on l	Note
No informa available			mation	No infori available		No informati available	on No inform available	ation
	~				(ow):	E I	_ .	NIsta
Value -	No	oncentration information ilable	рН -	•°C	Method No informatior available	Evalu No inforn available		Note
- Bic	No avai	information ilable entration factor	- (BCF)		Method No information available	No inform available	nation _	
- Bic Value	No avai	information ilable entration factor Speci	- (BCF) ies	•C	Method No information available Method	No inform available Evaluati	on	Note
- Bic	No avai	information ilable entration factor Speci	- (BCF)	•C	Method No information available Method formation	No inform available	on	Note
- Bic Value No informa	No avai	information ilable entration factor Spec No ir	- (BCF) ies	°C −	Method No information available Method formation	No inform available Evaluati No informati	on on No inform	Note
- Bic Value No informa available	No avai	information ilable entration factor Spec No ir	- (BCF) ies	°C −	Method No information available Method formation	No inform available Evaluati No informati	on on No inform	Note
- Bic Value No informa available Ch	No avai	information ilable entration factor Spec No ir available	- (BCF) ies iformatic	°C −	Method No information available Method formation	No inform available Evaluati No informati	on on No inform	Note



Page 12 of 15

Turneline		_		CDANA			CTADU	1750	Fage 1	.2 of 15
	g name:		C OT V++							_
Produc	t code:	GL	S-OT-X**	Date	of compilat	ion:]	L1 June 2	019.	Versio	n: 4
Chronic toxicity on crustacea (<i>Daphnia</i>) EC ₅₀		EC ₅₀	information	No information available	No inform availal	hation	No infor available		-	
12.4.	Mobilit	ty in soil								
	Known	or pred	icted distributi	on in environme	ental compar	tments:				
	No info	ormatior	n available							
	Surface	e tensior	1:							
	Val	Value °C Concentration Method			No	ote				
	No No information information available available		information	No informati available		n No information available				
	Adsorp		esorption		I					
Transpo	ort		oefficient s constant	log Kow	Evaporat	ion rate	M	ethod		Note
Soil-wat	ter N	o vailable	information	No information available	n No inforr available	nation	No info availab	ormatior le	ר -	
Water-a	air N av	o vailable	information	No information available	n No inforr available	nation	No info availab	ormatior le	ר י -	
Soil-air	N av	o vailable	information	No information available	n No inforr available	nation	No information available		ר -	
	1									
12.5.	Results	of PBT	and vPvB asses	ssment						
	No info	ormatior	n available							
10-5	_ ·									
12.6.		adverse								
	INO INTO	ormatior	n available							
SECTIO	N 13 DI	SPOSAL		ΠΟΝ						
13.1.			nent methods							
_0.2.										
13.1.1.	Prod	uct/Pack	kaging disposa	l:						
	Subn			egal person auth	norized by th	e Minist	ry of Envi	ronmen	tal and Na	ature

Page 13 of 15

Trading	g name: GRAM LUGOL SOLUTION, STABILIZED						
Product	code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4		
13.1.2.	Waste c	odes/waste designatio	ons according to Law:				
	No infor	mation available					
13.1.3.	Waste tr	eatment – relevant in	formation:				

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

> Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.

13.1.6. Relevant Community provisions:

_

SECTION 14 TRANSPORT INFORMATION

Transporting/shipment by road (ADR)		
UN number:	Not subject to transport regulations.	
UN proper shipping name:	-	
Transport hazard class(es):	-	
Packing group:	-	
Environmentally hazardous:	-	
Special precautions for user:	-	
Transporting/shipment by rail (RI	(D)	
UN number:	Not subject to transport regulations.	
UN proper shipping name:	-	
Transport hazard class(es):	-	
Packing group:	-	
Environmentally hazardous:	-	
Special precautions for user:	-	
Inland waterway transport (ADN)		
UN number:	Not subject to transport regulations.	
UN proper shipping name:	-	
Transport hazard class(es):	-	
Packing group:	-	

SAFETY DATA SHEET SAFETY DATA SHEET BIOGNOST[®] According to Regulation (EC) No. 1907/2006

Page 14 of 15

Trading name:	GRAM LUGOL SOLUTION, STABILIZED						
Product code:	GLS-OT-X**	GLS-OT-X**		11 June 2019.	Version:	4	
	1		1	3			
Environmentally ha	zardous:	-					
Special precautions	s for user:	-					
Transporti	ing/shipment by sea	(IMDG)					
UN number:		No	t subject to transport regu	lations.			
UN proper shippin	g name:	-					
Transport hazard c	lass(es):	-					
Packing group:		-					
Environmentally ha	zardous:	-					
Special precautions	s for user:	-					
Transporti	ing/shipment by air	(ICAO-1	I/IATA-DGR)				
UN number:	Not subject to transport regulations.						
UN proper shippin	g name:	-					
Transport hazard c	lass(es):	-					
Packing group:		-	-				
Environmentally hazardous: -			-				
Special precautions	s for user:	-					
Further information	n: The product	is not s	subject to classification.				

SECTIO	SECTION 15 REGULATORY INFORMATION						
15.1.	Safety, health and enviror	Safety, health and environmental regulations/legislation specific for the substance or mixture					
	EU regulations						
	Authorization and/or rest	rictions of use					
	Authorizations:	-					
	Restrictions:	-					
		EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;					
	Other EU regulations:	The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);					
		EC Regulation No. 2037/200 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;					
		EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;					
		EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;					
		Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives					

SAFETY DATA SHEET

BIOGNOST[®] According to Regulation (EC) No. 1907/2006

Page 15 of 15

Trading name:	GRAM LUGOL SOLUTION, STABILIZED						
Product code:	GLS-OT-X**	Date of compilation:	11 June 2019.	Version: 4			

	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC- guideline)					
	National legislation: Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act					
15.2.	Chemical safety assessment					
	None					

SECTIC	SECTION 16 Other information					
16.1.	Indication of changes:	-				
		PBT	Stable, bioaccumulative and toxic			
		vPvB	Strongly stable and strongly bioaccumulative.			
16.2.	Abbreviations and acronyms:	LD ₅₀	Lethal dose, 50%			
		LC ₅₀	Lethal concentration, 50%			
		STOT-SE	Specific target organ toxicity - single exposure			
16.3.	Key literature references and source of data:	-				
16.4.	Classification and procedure u 1272/2008 (CLP)	sed to derive the	e classification for mixture according to Regulation (EC)			
Classifi	cation	Classification pro	ocedure			
-		-				
16.5.	Relevant H statements (numbe	er and full text)				
	H: -	-				
16.6.	Training advice:	-				
		** "X" in the product code marks different volumes (different packagings of the product)				
16.7.	i	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



Page 1 of 17

Trading name:	GRAM DECOLORIZER SOLUTION 2						
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4			

SECTI	ON 1: Identification of t	he substance	e/mixture	and of the company/undertaking		
1.1	Product identifier					
	Trading name:	GRAM DEC	OLORIZER	SOLUTION 2		
	Chemical name:	-				
	Catalogue number:	GD2-OT-X*	*			
1.2	Relevant identified use	s of the subs	tance or m	nixture and uses advised against		
	Uses:		For use i	in Gram bacterial staining.		
	Uses advised against:		Only the	identified uses are advised.		
	Reason why uses advis	ed against:	against: The product is intended for use only as an <i>in vitro</i> diagnost medical device, registered at the Agency for Medicinal Products an 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. Medjugorska 59, Zagreb +385 1 2409997			
	Address:					
	Telephone number:					
	Telefax.:		+38512	2404039		
	e-mail of competent p	erson:	<u>msds@b</u>	<u>biognost.hr</u>		
	National contact:		-			
1.4	Emergency telephone	number				
	National Protection an	d Rescue Dire	ectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	ON 2. Hazards identification			
2.1	Classification of the substance	e or mixture		
2.1.1	Classification according to Re	gulation (EC) No	1272/2008 (CLP)	
	Hazard class and cate	gory code:	Hazard statements*:	
	Flam. Liq. 2		H225	
	Eye Irrit. 2		H319	
	STOT SE 3		H336	
			EUH066	
2.1.2.	Additional information			
	-			
*For fu	II text of Hazard- and EU Hazard	d-statements: see	e SECTION 16	
2.2	Label elements			
	Product identification:	GRAM DECOL	LORIZER SOLUTION 2	
	Identification number:	-		



Page 2 of 17

Trading name:	GRAM DECOLORIZER SOLUTION 2					
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4		

	Authorization number:	-
	Hazard pictograms:	GHS02 GHS07
	Signal word:	Danger
	Hazard statements:	 H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. EUH066 Repeated exposure may cause skin dryness or cracking.
	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	
	-	

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- xxxx	≤ 50 %	ethanol	Flam. Liq. 2; H225			
67-64-1/ 200-662-2/ 606-001-00-8	-	≥ 50 %	acetone	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336			

SECTIO	SECTION 4. First aid measures	
4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	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.



Page 3 of 17

Trading name:	GRAM DECOLORIZER SOLUTION 2				
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4	

	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:	Do not induce vomiting. Do not insert any object into the unconscious person's mouth. 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:	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 medi	cal attention and special treatment needed
	-	

SECTIC	SECTION 5. Firefighting measures		
5.1	Extinguishing media		
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam	
	Unsuitable extinguishing media:	No information available.	
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. Additional information Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.		
5.4			

SECTION 6. Accidental release measures	
6.1	Personal precautions, protective equipment and emergency procedures
6.1.1.	For non-emergency personnel



Page 4 of 17

Trading name:		GRAM DECOLORIZ	ZER SOLUTION 2	
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4

	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 ((see Section 8).	case of inadequate ventilation use adequate airways protective equipment			
6.2	Environmental precautions:				
	Do not dispose of in sewage, Protection and Rescue Directo	drainage system and waterways. In case of large spillage contact National orate (NPRD) on 112.			
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:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.			
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).			
6.4	Reference to other sections				
	See Section 7 for information See Section 8 for information See Section 13 for disposal int	on personal protection equipment.			

SECTIO	DN 7. Handling and storage	
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.
	Measures to prevent aerosol and dust generation:	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. Thoroughl	y wash hands after work and before eating.



Page 5 of 17

Trading name:		GRAM DECOLOR	RIZER SOLUTION 2		
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4	

7.2	Conditions for safe storage, including any incom	npatibilities
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.
	Packaging materials:	Manufacturer's original packaging. Unsuitable material for receptacle: aluminium.
	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. Exp	osure contr	ols/perso	onal pr	otect	ion			
8.1 Control	parameters							
Substance		CA	CAS No		Occupational exposure limit values/short term values		•	Biological limit values
					рр	m	mg/m ³	
Ethanol		64	-17-5		100	0/-	1900/-	-
								20.0 mg/L (0.34 mmol/L), blood, end of shift
Acetone		67	-64-1		500)/-	1210/-	20.0 mg/g of creatinine (39.0 mmol/mol of creatinine), urine, end of shift
Substance name	-							
EC No:	-	CAS No	:	-				
DNEL								
					Indus	strial		
Route of exposure:	Acu effect		effe	Acute ct syst	-		Chronic effect local	Chronic effect systemic
Oral	-		-			-		-



Page 6 of 17

				Page 6 of 17				
Trading name	e:		GRAM	M DECOLORIZER SOLUTION 2				
Product code	e: G	GD2-OT-X**	Revisi	on date:	11 June 2019	Version: 4		
			-					
Inhalation	-		-	-		950 mg/m ³ (ethanol) 1210 mg/m ³ (acetone)		
Dermal	-		-	-		343 mg/kg (ethanol) 186 mg/kg (acetone)		
Critical physica	al paran	neters: solubility,	l flammability_co	rrosivity.	_	(accenter)		
	ai paran		,	onsumer				
Route of		Acute	Acute		Chronic	Chronic		
exposure:		effect local	effect system	ic e	effect local	effect systemic		
Oral		-	-	-		-		
Inhalation		-	-	-		114 mg/m ³ (ethanol) 200 mg/m ³ (acetone)		
Dermal		_	_	_		206 mg/kg (ethanol)		
Dermai		-	-			62 mg/kg (acetone)		
PNEC				1				
Environmental protection target				PNEC				
Fresh water				0.96 mg/l (ethanol) 10.6 mg/l (acetone)				
Freshwater sec	diments			3.6 mg/kg (ethanol)				
				30.4 mg/kg (acetone)				
Marine water				0.79 mg/l (ethanol) 1.06 mg/kg (acetone)				
Marine sedime	ents			3.04 mg/kg	(acetone)			
Food chain				no informa	tion available			
Microorganism	ns in sev	wage treatment		100 mg/l (a	icetone)			
Soil (agricultur	ral)			0.63 mg/kg (ethanol)				
	ui)			29.5 mg/kg (acetone)				
Air				no information available				
8.2 Ex	xposure	controls						
8.2.1. Appropriate engineering controls								
Substance/mixture related measures to prevent exposure during identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.						
	tructura xposure	l measures to pre :	event	In accordance with Section 7.				
	rganisa xposure	tional measures t	to prevent		on of work in orde uring work proces	r to reduce other worker's ss.		



Page 7 of 17

Trading name:		GRAM DECOLOR	ZIZER SOLUTION 2	
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4

	Technical measures to prevent ex	posure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.			
8.2.2.	Personal protection equipment					
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.				
8.2.2.2.	Skin protection					
	Hand protection:	Regula Full co	otective gloves have to satisfy the specification of tion (EU) 2016/425 and the related standard EN 374. ntact: Glove material: butyl rubber Glove thickness: ≥ 0.50 mm Time until perforation: > 480 min contact: Glove material: nitrile rubber Glove thickness: 0.4 mm Break through time: 35 min			
	Other skin protection:	suitabl cover t of imp	everyday work use antistatic clothing (EN 13688) and e footwear, such as rubber boots (EN 20345) or shoes that the entire foot. In case of spilling hazard, use clothing made ermeable material suitable for protection from liquid cals (Viton, PVC, himex) and footwear made from the same al.			
8.2.2.3.	Respiratory protection:	inadeq	concentration level exceeds the GVI values (or because of uate ventilation), use a filter for organic vapors, type "A" g point >65°C) according to EN 14387.			
8.2.2.4.	Thermal hazards:	No info	ormation available			
8.2.3.	Environmental exposure controls					
	Substance/mixture related measures to prevent exposure:	See Se	ction 6			
	Structural measures to prevent exposure:	Use m	odern equipment.			
	Organisational measures to prevent exposure:	Adapt workpl	the work process to the required working conditions of the ace.			
	Technical measures to prevent exposure:	See Section 6				

SECTIC	SECTION 9. Physical and chemical properties		
9.1	Information on basic physical and ch	emical properties	
		Value	Method



Page 8 of 17

Trading name:		GRAM DECOLOR	RIZER SOLUTION 2	
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4

Physical state:	liquid	No information available
Colour:	colourless	No information available
Odour:	aceton like	No information available
Odor threshold:	No information available	No information available
pH:	No information available	No information available
Melting point / freezing point;	No information available	No information available
Initial boiling point and boiling range:	No information available	No information available
Flash point:	20°C	No information available
Evaporation rate:	No information available	No information available
Flammability (solid, gas):	No information available	No information available
Upper/lower flammability or explosive limits:	No information available	No information available
Vapour pressure:	No information available	No information available
Vapour density:	No information available	No information available
Relative density:	No information available	No information available
Bulk density:	No information available	No information available
Solubility(ies):	Soluble (20°C)	No information available
Partition coefficient: n- octanol/water (log Kow):	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
Viscosity:	No information available	No information available
Explosive properties:	No information available	No information available
Oxidising properties:	No information available	No information available

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



Page 9 of 17

Trading name:		GRAM DECOLORIZ	ZER SOLUTION 2		
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4	

	on toxicolog						
Acute toxici	ty:		1				
Route of exposure:	Method	Species		LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposui time	re	Results
Oral:	-	rat		LD ₅₀	-		060 mg/kg (ethanol) ,000 mg/kg (acetone)
Dermal:	-	rat		LD ₅₀	-	>2,	,000 mg/kg (acetone)
Inhalation:	-	rat		LC ₅₀	4 h		0.000 mg/l (ethanol) 20 mg/l (acetone)
Specific targ	jet organ toxi	city – single ex	(posure (S	STOT SE):			
	Sp	ecific effects		Tar	get orgar	n	Note
Oral:	No informati	on available		No informa	tion availa	able	-
Dermal:	No informati	on available		No informa	tion availa	able	-
Inhalation:	No informati	on available		No informa	may cause drowsiness or dizziness		
Aspiration h	azard:		No infor	mation availa	ble.		
Aspiration h	azard: d corrosion	sure time	No infor		ble.	Method	Note
Aspiration h	azard: d corrosion	sure time				Method	
Aspiration h Irritation an Skin	azard: d corrosion	sure time	Spec	ies Eva		Method -	
Aspiration h Irritation an Skin corrosion/irritation: Serious eye	azard: d corrosion Expos - -	sure time	Spec	ies Eva -		Method - -	Note - causes serious eye
Aspiration h Irritation an Skin corrosion/irritation: Serious eye damage/irritation Sensitization	azard: d corrosion Expos - -	sure time	Spec - -	ies Eva -		Method - -	Note - causes serious eye
Aspiration h Irritation an Skin corrosion/irritation: Serious eye damage/irritation	azard: d corrosion Expos - -		Spec - - vailable.	ies Eva -		Method -	Note - causes serious eye
Aspiration h Irritation an Skin corrosion/irritation: Serious eye damage/irritation Skin sensitization: Respiratory sensitizat	azard: d corrosion Expos - - n No tion: No	information av	Spec - - vailable. vailable.	ies Eva - -	luation	-	Note - causes serious eye
Aspiration h Irritation an Skin corrosion/irritation: Serious eye damage/irritation Skin sensitization: Respiratory sensitizat Symptoms r	azard: d corrosion Expos - - n No tion: No	information av	Spec - - railable. railable.	ies Eva - -	luation	-	Note - causes serious eye
Aspiration h Irritation an Skin corrosion/irritation: Serious eye damage/irritation Skin sensitization: Respiratory sensitizat	azard: d corrosion Expos - - No tion: No related to the No inform	information av information av physical, chem	Spec - - vailable. vailable. inical and t	ies Eva - -	luation	-	Note - causes serious eye
Aspiration h Irritation an Skin corrosion/irritation: Serious eye damage/irritation Skin sensitization: Respiratory sensitizat Symptoms r Oral exposure:	azard: d corrosion Expos - - No tion: No related to the No inform No inform	information av information av physical, chem ation available	Spec - - vailable. vailable. inical and t	ies Eva - -	luation	-	Note - causes serious eye



Page 10 of 17

Trading name:		GRAM DECOLORIZER SOLUTION 2				
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4		

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

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



Page 11 of 17

Trading name:		GRAM DECOLORIZER SOLUTION 2					
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4			

	CMR effects (carcinogenicity; mutagenicity;	reproductive toxicity)				
	Carcinogenicity: B	Based on available data, the classification criteria are not met.				
	Mutagenicity <i>in vitro</i> : B	ased on available data, the classification criteria are not met.				
	Genotoxicity: B	ased on available data, the classification criteria are not met.				
	Mutagenicity <i>in vivo</i> : B	ased on available data, the classification criteria are not met.				
	Germ cell mutagenicity: B	ased on available data, the classification criteria are not met.				
	Reproductive toxicity: B	Based on available data, the classification criteria are not met.				
	Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.				
11.2	Practical experiences:					
	Classification observations:	No information available				
	Other observations:	No information available				
11.3	General notes:					
	-					

SECTION 12. Ecological information											
12.1 Toxicity											
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note					
Fish	LC ₅₀	96 hours	No information available	No information available	-	-					
Crustacea:	EC ₅₀	48 hours	Daphnia magna	No information available	>1,000 mg/l (acetone)	-					
Algae/aquatic plants	IC ₅₀	4 days	algae	No information available	>1,000 mg/l (acetone)	-					
Other organisms	-	-	-	-	-	-					
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note					
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-					



Page 12 of 17

					Pag	e 12 of 17			
Trading name:			GRAM DECOLORIZER SOLUTION 2						
Product code:	GD2-01	Г-Х**	Revision date:	11 June 20	019 Ve	Version: 4			
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	۱ -			
Algae/aquatic pl	ants IC ₅₀	72 hours	No information available	No information available	No information available] _			
Other organisms	; -	-	-	-	-	-			
12.2 Persiste	nce and deg	radability							
	degradation	-							
	-	ion half-lives	Method	Evaluatio	'n	Note			
Marine water		tion available	No information available	No informatio available	n -				
Fresh water	No informat	tion available	No information available	No informatio available	n _				
Air No information available		tion available	No information available	No informatio available	n -	-			
Soil No information available		No information available							
Biodear	radation								
% Degradation		ime (days)	Method	Evaluatio	n	Note			
No information available	No availab	information	No information availableNo information available		n No info	No information available			
12.3 Bioaccu	imulative pot	tential							
	•	tion coefficient (-	_	_				
Value (Concentratio	•	°C Method		lation	Note			
				-	-				
	centration fac								
No information	No	information	No information	No informati		Note			
Value No information available			Method No information available	Evaluati No informati available		Not			



Page 13 of 17

Tradin	a nam	٥.		CPAN						Page 13 of 17			
Trading name: Product code:			GD2-OT-X**		GRAM DECOLORIZER SOLUTION 2 Revision date: 11 June 2019			L	Version: 4				
			D2-01-X	REVIS	ion ua	ite.		ine 2019		VEISION, 4			
		i		·			1		I				
	Chro	nic ecoto	xicity										
	Valu	Je	Dose	Exposure time	Spe	cies	Meth	nod I	Evaluation	Note			
Chroni	c toxicit	ty on fish	LC ₅₀	No information available	No inform availal		No inform availab		o formation ailable	-			
	c toxicit cea (<i>Da</i> j		EC ₅₀	No information available	No inform availal		No inform availab		o formation vailable	-			
			i							ł			
12.4	Mobi	ility in so	il										
	Know	Known or predicted distribution in environmental compartments:											
	No information available												
	Surfa	ce tensic	n:										
	Value		°C	Concentrat	ion	n Method		od		Note			
	No infori availa	mation able	No information available	No informati available	ion	No info availat	formation -						
	Adso	rption / a	desorption		i								
		-	coefficient										
Transp	ort		's constant	log Kow	Eva	aporatio	on rate Method		hod	Note			
Soil-wa	ator 👘	No available	information	No informatio available		No information available		No information available		-			
Water-	Water-air No information available			No informatio available	-	inform ailable	nation	No infor available		-			
Soil-air No information available		No informatio available		inform ailable	ation No information available			-					
12.5	Resul	ts of PBT	and vPvB asses	ssment									
	Not a	applicable	2.										
12.6	Othe	r adverse	effects										
	No further relevant information available.												



				Page 14 of 17			
Trading name:		GRAM DECOLOF	RIZER SOLUTION 2				
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4			
	sposal considerations e treatment methods						
IS.I Waste							
13.1.1. Produ	ct/Packaging disposal:						
Subm Prote		al person authorized by th	e Ministry of Environme	ental and Nature			
13.1.2. Waste	e codes/waste designati	ons according to Law:					
Packa	ging that contains resid	ual hazardous substances	or is contaminated with	hazardous substances			
13.1.3. Waste	e treatment – relevant ir	formation:					
	formation available						
÷							
13.1.4. Sewag	ge disposal – relevant in	formation:					
Waste	e must not be disposed	of into the sewage system.					
13.1.5. Other	disposal recommendat	ions:					
Do no autho	ot dispose of the produc rized by the ministry in	t's remains into the sewag charge. Do not dispose of rs authorized by the minist	the packaging into the				
	ant Community provisio						
Dispo	sal must be made accor	cording to official regulations.					
	ANSPORT INFORMATI						
UN number:	orting/shipment by road	(ADR) 1170					
UN proper shipp	ing name:	Ethanol solution					
Transport hazard		3					
Packing group:		I					
Environmentally	hazardous:	- -					
Special precaution		-					
	orting/shipment by rail (RID)					
UN number:		1170					
UN proper shipp	ing name:	Ethanol solution					
Transport hazard		3					
Packing group:		II					
с · и	hazardous:	_					



Page 15 of 17

Trading name:	GRAM DECOLORIZER SOLUTION 2					
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4		

Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	П
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IN	/IDG)
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:	П
Environmentally hazardous:	-
Special precautions for user:	-
Further information: -	

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



				Page 16 of 17
Trading name	2:	GRAM DECOLO	RIZER SOLUTION 2	
Product code	: GD2-OT-X	** Revision date:	11 June 2019	Version: 4
Other	EU regulations:	EC Regulation No. 1906/200 European Parliament and the Regulation (EC) No. 1907/200 registration, evaluation, author (REACH); EC Regulation No. 2037/200 29 June 2000 on substances EC Regulation No. 689/2008 17 June 2008 concerning the EC Regulation No. 850/2004 29 April 2004 about persisted Directive 2008/98/EC of the November 2008 on waste a	e European Council; 206 of the European Par horization and restrictio 2 of the European Parlia 5 that damage the ozone 3 of the European Parlia e export and import of 6 4 of the European Parlia ent organic pollutants; European Parliament a	liament and Council on n of chemical substances ment and Council from e layer; ment and Council from dangerous chemicals; ment and Council from nd Council of 19
Inforn guide	-	1999/13/EC about limitation of em	issions of volatile organ	ic compounds (VOC-
Natio	nal legislation:	Chemicals Act, Regulation of dangerous substances, Ordi and on biological limit value classification of waste with a Ordinance on writing Mater	nance on occupational es, Regulation on catego a waste catalog and list	exposure limit values pries, types and of hazardous waste,

	Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment
	None

SECTIO	SECTION 16. Other information				
16.1	Indi	cation of changes:	-		
16.2	Abt	previations and acronyms:	PBT vPvB LD ₅₀ LC ₅₀ TCOJ	Stable, bioaccumulative and toxic Strongly stable and strongly bioaccumulative. Lethal dose, 50% Lethal concentration, 50% Specific target organ toxicity - single exposure	
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)			he classification for mixture according to Regulation (EC)	
Classifi	catior	١	Classification p	rocedure	
-			-		
16.5.	Rele	evant H statements (numb	er and full text)		
		H225	Highly flammable liquid and vapor.		
	H:	H319	Causes serious eye irritation.		
		H336	May cause drowsiness or dizziness.		
		(EUH066)	Repeated expo	sure may cause skin dryness or cracking.	



Page 17 of 17

Trading name:	GRAM DECOLORIZER SOLUTION 2					
Product code:	GD2-OT-X**	Revision date:	11 June 2019	Version: 4		

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



Page 1 of 16

Trading name:	GRAM SAFRANIN SOLUTION						
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5		

SECTI	ON 1: Identification of t	he substance	e/mixture	and of the company/undertaking	
1.1	Product identifier				
	Trading name:	GRAM SAF	RANIN SO	LUTION	
	Chemical name:	-			
	Catalogue number:	GSF-OT-X**	*		
1.2	Relevant identified uses of the substance or mixture and uses advised against				
	Uses:	n Gram staining using BioGram 4 kit.			
	Uses advised against:		Only the	identified uses are advised.	
	Reason why uses advis	dvised against: The product is intended for use only as an <i>in vitro</i> diagnost medical device, registered at the Agency for Medicinal Proc Medical Devices and there is no reason to use it for other p			
1.3	Details of the supplier	of the safety	data sheet	t	
	Supplier:	Supplier:		BioGnost Ltd.	
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2404039		
	e-mail of competent p	erson:	msds@biognost.hr		
	National contact:		-		
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 F	Regulation (EC) No 12	L272/2008 (CLP)			
	Hazard class and category code: Hazard statements*:					
	Flam. Liq. 3		H226			
2.1.2.	Additional information					
	-					
*For fu	ll text of Hazard- and EU Haza	ird-statements: see S	SECTION 16			
2.2	Label elements					
	Product identification:	GRAM SAFRANI	JIN SOLUTION			
	Identification number:	-				
	Authorization number:	-				



Page 2 of 16

Trading name:	GRAM SAFRANIN SOLUTION						
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5		

	Hazard pictograms:	GHS02
	Signal word:	Warning
	Hazard statements:	H226 Flammable liquid and vapor
	Precautionary statements:	 P210 Keep away from heat/sparks/open flames/hot surfaces Do not smoke. P233 Keep container tightly closed. P281 Use personal protective equipment as required.
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	-	

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- xxxx	<10 %	ethanol	Flam. Liq. 2; H225	

SECT	SECTION 4. First aid measures				
4.1	Description of first aid measu	ıres			
	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 oral cavity, drink 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.			



Page 3 of 16

Trading name:	GRAM SAFRANIN S		SOLUTION		
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5

	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.	
4.3	Indication of any immediate medi	cal attention and special treatment needed	
	-		

SECTIO	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the substance or mixture				
	Hazardous combustion products:	Incomplete combustion of the product.			
5.3	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.				
5.4	Additional information				
	Do not contaminate the environm	ent with extinguishing media.			

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



Page 4 of 16

Trading name:	GRAM SAFRANIN SOLUTIO		SOLUTION		
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5

	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 cor	ntainment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.	
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.	
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).	
6.4	Reference to other sections		
	See Section 7 for information on safe handling.		
	See Section 8 for information	on personal protection equipment.	
	See Section 13 for disposal information.		

SECTIO	SECTION 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:		Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks.		
	Measures to prevent aerosol and dust generatio	n:	Secure proper ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:		-		
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. The	oroughly was	sh hands after work and before eating.		
7.2	Conditions for safe storage, including any incom	patibilities			
	Technical measures and storage conditions:		htly closed and upright set containers in a ated storage roomsat temperatures ranging 25 °C.		
	Packaging materials:	Manufactu	ırer's original packaging.		
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the container tightly closed.			
	Advices for storage equipment:	must be re	e must be made of hard material; floors esistant to chemicals. There must be no drain ly leads into sewage system. Secure proper n.		



Page 5 of 16

Trading name:	GRAM SAFI		GRAM SAFRANIN SOLUTION		
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5

	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:	-

SECTIC	ON 8. Expos	ure contro	ols/perso	onal prote	ction				
8.1	Control pa	rameters							
	Substance		CA	S No		Occupational exposure limit values/short term values			Biological limit values
					pp	om	n	ng/m ³	
Ethano			64	-17-5	100	00/-	1	900/-	-
Substa	nce name:	_							
EC No:	ice name.	_	CAS No	· _					
DNEL									
DITLE					Indu	strial			
Route	of	Αcι	ıte	Αсι			Ch	ronic	Chronic
exposu	ıre:	effect	local	effect sy	/stemic		effe	ct local	effect systemic
Oral		-		-		-			-
Inhalati	ion	-		-		-			950 mg/m ³ (ethanol)
Dermal		-		-		- 343 mg/kg (etha		343 mg/kg (ethanol)	
Critical	physical par	ameters: s	olubility,	flammabil	ity, corro	sivity:		-	
					Cons	umer			
Route	-	Ac		Acute		Chronic			Chronic
exposu	ire:	effect	local	effect syst	emic	6	effect	local	effect systemic
Oral		-		-	-				-
Inhalati	ion	-		-	-				114 mg/m ³ (ethanol)
Dermal		-		-	-				206 mg/kg (ethanol)
PNEC									
Environ	nmental prot	ection tar	get		P	NEC			
Fresh w	vater				0	0.96 mg/l (ethanol)			
Freshwa	ater sedimer	nts			3	3.6 mg/kg (ethanol)			
Marine	water				0	0.79 mg/l (ethanol)			
Marine	sediments				n	no information available			



Dago 6 of 16

Trading name:		GRAM SAFRANIN	SOLUTION				
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5		
Food chain		no information a	available				
Microorganisms i	n sewage treatment	no information a	no information available				
Soil (agricultural)		0.63 mg/kg (eth	0.63 mg/kg (ethanol)				
Air		no information a	available				

8.2	Exposure controls					
8.2.1.	Appropriate engineering controls					
	Substance/mixture related measu prevent exposure during identifie		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to prevent exposure:		In accordance with Section 7.			
	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent ex	posure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.			
8.2.2.	Personal protection equipment					
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.				
8.2.2.2.	Skin protection					
	Hand protection:	•	otective gloves have to satisfy the specification of tion (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Break through time: > 480 min			
	Other skin protection:	footwe entire f impern	everyday work use cotton clothing (EN 340) and suitable ear, such as rubber boots (EN 20345) or shoes that cover the foot. In case of spilling hazard, use clothing made of neable material suitable for protection from liquid chemicals PVC, himex) and footwear made from the same material.			
8.2.2.3.	Respiratory protection:	Suitable mask (EN 136) or half mask (EN 140) equipped with a filt for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.				
8.2.2.4.	Thermal hazards:	No info	ormation available			
8.2.3.	Environmental exposure controls					
	Substance/mixture related measures to prevent exposure:	See Se	ection 6			



Page 7 of 16

Trading name:	GRAM SAFRANIN SOLUTION							
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5			

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

1	Information on basic physical and	chemical properties	
		Value	Method
	Physical state:	liquid	No information available
	Colour:	red	No information available
	Odour:	ethanol like	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point;	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	49 °C	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	Soluble in water (20 °C)	No information available
	Partition coefficient: n- octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available



Respiratory sensitization:

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

Page 8 of 16

Trading name:		GRAM SAFRANIN S	OLUTION		
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5

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:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.				
10.4	Conditions to avoid:	High temperatures, ignition sources, open flame.				
10.5	Incompatible materials:	Oxidants, acids, alkali metals.				
10.6	Hazardous decomposition products:	Non-degradable if used in the described manner.				

SECTION 11. Toxic 11.1 Informatio		ogical effects					
Acute toxic		ogical criccis					
Route of exposure:	Method	Species	Do	ose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure ti	me	Results
Oral:	-	rat (ethano	l)	LD ₅₀	-		7.060 mg/kg
Dermal:	-	_		-	-		-
Inhalation:	-	rat (ethano	l)	LC ₅₀	4 h		20.000 mg/l
Specific ta	rget organ t	oxicity – single ex	kposure (S	TOT SE):			
		Specific effects		Target o	organ		Note
Oral:	No inform	ation available	No information available -			-	
Dermal:	No inform	ation available	No information available -				
Inhalation:	No inform	ation available	No information available -				
Aspiration	hazard:		No infor	mation available.			
÷							
Irritation a	nd corrosior	ו					
	Exp	posure time	Spec	ies Evaluati	on Method		Note
Skin corrosion/irritation:	-		-	-	-	-	
Serious eye damage/irritation	-		_	-	-	-	
Sensitizatio	on						
Skin sensitization:		lo information av	vailable.				
		_					

No information available.



Page 9 of 16

								Page 9 of 1	6
Trading name:				GRAM SAFRA	ANIN S	OLUTIO	N		
Product code:		F-OT-X**	Da	Date of compilation:		11 June 2019		Version:	5
Sympto	ms rela	ated to the ph	vsical chemic	al and toxicolog	ical cha	racteristi	rs		
Oral exposure:		No informati			ji car ciria				
Dermal exposure	:	No informati							
Inhalation exposi		No informati	on available.						
Eye exposure:		No informati	on available.						
Panasta	d doce	tovicity (cub	acute, subchro	nic chronic)					
Repeate		Dose	Exposure time	Species	Meth	bc	Evaluation	n Note	
Subacute oral	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
Subacute dermal	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
Subacute inhalation	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
Subchronic oral	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
Subchronic dermal	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
Subchronic inhalation	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
Chronic oral	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
Chronic dermal	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
Chronic inhalation	No availa	information able	No information available	No information available	No inforr availa	nation ble	No informatic available	on -	
C • • •									
Specific	target	organ toxicit	, ,	xposure (STOT		T ·			
Subscrite and		No:	Specific effec	TS		Target o	-	Note	
Subacute oral Subacute dermal			tion available				i available i available	-	

Page 10 of 16

Trading name:	GRAM SAFRANIN SOLUTION						
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5		

Subacute inhalation		No information available		No information available	-		
Subchronic oral		No information available		No information available	-		
Subch	ronic dermal	No information available		No information available	-		
Subch	ronic inhalation	No information available		No information available	-		
Chroni	c oral	No information available		No information available	-		
Chroni	c dermal	No information available		No information available	-		
Chroni	c inhalation	No information available		No information available	-		
	CMR effects (c	arcinogenicity; mutagenicity; re	eproductive t	oxicity)			
	Carcinogenicit	y:	No informa	tion available			
	Mutagenicity i	n vitro:	No information available				
	Genotoxicity:		No information available No information available No information available No information available				
	Mutagenicity i	n vivo:					
	Germ cell muta	agenicity:					
	Reproductive t	toxicity:					
	Summary of properties:	evaluation of the CMR					
11.2	Practical exper	iences:					
	Classification of		No informa	ation available			
	Other observations:		No informa	ation available			
11.3	General notes:						
	-						

SECTION 12. Ecologie	SECTION 12. Ecological information							
12.1 Toxicity								
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		
Fish	LC ₅₀	96 hours	-	-	-	-		
Crustacea:	EC ₅₀	48 hours	-	-	-	-		
Algae/aquatic plants	IC ₅₀	4 days	-	-	-	-		
Other organisms	-	-	-	-	-	-		
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		



Page 11 of 16

Trading name:		GRAM SAFRANIN	SOLUTION		
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5

Fish	LC ₅₀ 96 hours		No information available	No information available	No informat available		
Crustacea:		EC ₅₀	48 hours	No information available	No information available	No informat available	
Algae/aquatic p	lants	IC ₅₀	72 hours	No information available	No information available	No informat available	
Other organism	IS	-	-	-	-	-	-
12.2 Persist	ence a	nd degrad	ability				
		adation					
i	De	egradation	half-lives	Method	Evaluatio	on	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		
Biodec	radati	00					
% Degradatio			(days)	Method	Evaluatio	on	Note
No information available		No information available		No information available	No information available		lo information vailable
12.3 Bioacc	umula	tive potent	ial				

Octanol-water partition coefficient (log Kow)	

Value	Concentration	рН	°C	Method	Evaluation	Note
-	-	-	-	-	-	-
	:			-	1	:
Biod	concentration factor	(BCF)				
Value	Spec	ioc		Method	Evaluation	Note



Page 12 of 16

	me:			GR	AM S	AFRAI	NIN SO	LUTIC	DN			
Product co	de: G	SF-OT-X**	Date of compilation:		on:	11 June 2019		9	Version:	ļ		
No informat available		o inform railable	ation	No information available		No information available		-				
Ch	ropic ocoto											
1	ronic ecoto alue	Dose		osure ime	Spe	cies	Metł	nod	Eva	luation	Note	e
Chronic toxicity on fish LC ₅₀			No No information info		nation ble	No inform availab		No inforr availa	nation able	-		
Chronic toxicity on crustacea (<i>Daphnia</i>)		EC ₅₀	No N information in		No inform availa	nation ble	No inform availab	No mation inf		mation able	-	
	Value ormation ailable	°C No information available	Concentration No information available						- Note			
Ad	sorption /	desorption										
Transport	-	coefficient y's constant	lo	og Kow	Ev	aporati	on rate		Metho	d	Note	
oil-water No information available			No ir availa	nformation able	-	inform ailable	nation	No information available		tion	-	
Soil-water	ater-air No information available		No information available			No information available		n No informa available		tion	-	
Soil-water Water-air	-		availa	able	avo	ailable		uvun	abic			



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

Page 13 of 16

Tradir	ng name:		GRAM SAFRANIN	SOLUTION		
Produ	ict code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5
	;					
12.6	12.6 Other adverse effects					
	No information available					

 SECTION 13. Disposal considerations

 13.1
 Waste treatment methods

 13.1.1.
 Product/Packaging disposal:

 Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

 13.1.2.
 Waste codes/waste designations according to Law:

Packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3.	Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.

13.1.6. Relevant Community provisions:

_

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by	road (ADR)
UN num	ıber:	1170
UN prop	per shipping name:	Ethanol solution
Transpo	rt hazard class(es):	3
Packing group:		ш
Environ	mentally hazardous:	-
Special	precautions for user:	-
	Transporting/shipment by	rail (RID)
UN num	ıber:	1170
UN prop	per shipping name:	Ethanol solution



Page 14 of 16

Trading name:	GRAM SAFRANIN SOLUTION					
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5	

Transport hazard class(es):	•	3
Packing group:		Ш
Environmentally hazardou	S:	-
Special precautions for use	er:	-
Inland waterway	transport (ADN)	
UN number:		1170
UN proper shipping name	:	Ethanol solution
Transport hazard class(es):	:	3
Packing group:		Ш
Environmentally hazardou	S:	-
Special precautions for use	er:	-
Transporting/ship	oment by sea (IN	/IDG)
UN number:		1170
UN proper shipping name	:	Ethanol solution
Transport hazard class(es):	:	3
Packing group:		Ш
Environmentally hazardou	S:	-
Special precautions for use	er:	-
Transport in bulk accordin of MARPOL 73/78 and the	0	-
Transporting/ship	oment by air (IC	AO-TI/IATA-DGR)
UN number:		1170
UN proper shipping name	:	Ethanol solution
Transport hazard class(es):		3
Packing group:		Ш
Environmentally hazardou	S:	-
Special precautions for use	er:	-
Further information:	volume is not s IATA: Special P	rovision 144 – An aqueous solution containing 24% or less alcohol by subject to classification. rovision A58 - An aqueous solution containing 24% or less alcohol by subject to classification.

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



Page 15 of 16

Trading name:		GRAM SAFRANIN	SOLUTION		
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5

	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	 EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/200 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
	Information according 1999 guideline))/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 assessment	
	None	

SECTIO	N 16. Other information		
16.1	Indication of changes:	-	
16.2	Abbreviations and acronyms:	PBT vPvB LD ₅₀ LC ₅₀ TCOJ	Stable, bioaccumulative and toxic Strongly stable and strongly bioaccumulative. Lethal dose, 50% Lethal concentration, 50% Specific target organ toxicity - single exposure
16.3.	Key literature references and source of data:	-	
16.4.	4. Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification pro	ocedure
-	-	-	
16.5.	Relevant H statements (numbe	er and full text)	



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

Page 16 of 16

Trading name:		GRAM SAFRANIN S	OLUTION		
Product code:	GSF-OT-X**	Date of compilation:	11 June 2019	Version:	5

	H: H225 H226	Highly flammable liquid and vapour. Flammable liquid and vapour.
16.6.	Training advice:	-
		** "X" in the product code marks different volumes (different packagings of the product)
16.7.	Further information:	We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to chemical safety assessment



Page 1 of 16

Trading name:		PICRIC ACID IN ACE	TONE, SOLUTION		
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4

SECTI	ON 1: Identification of t	he substance	e/mixture	and of the company/undertaking	
1.1	Product identifier				
	Trading name:	PICRIC ACIE	D IN ACET	one, solution	
	Chemical name:	-			
	Catalogue number:	PKA-OT-X*	k		
1.2	Relevant identified use	s of the subst	tance or m	nixture and uses advised against	
	Uses:		For use v	with H.B.F.P. kit.	
	Uses advised against:		Only the	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 sheet	t	
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997		
	Telefax.:		+385 1 2	2404039	
	e-mail of competent p	erson:	<u>msds@b</u>	<u>biognost.hr</u>	
	National contact:		-		
1.4	Emergency telephone	number			
	National Protection an	d Rescue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	ON 2. Hazards identification			
2.1	Classification of the substance	e or mixture		
2.1.1	Classification according to Re	gulation (EC) No	o 1272/2008 (CLP)	
	Hazard class and cate	gory code:	Hazard statements*:	
	Flam. Liq. 2		H225	
	Eye Irr. 2		H319	
	STOT SE 3		H336	
			EUH066	
2.1.2.	Additional information			
	-			
*For fu	ll text of Hazard- and EU Hazard	d-statements: se	e SECTION 16	
2.2	Label elements			
	Product identification:	PICRIC ACID	IN ACETONE, SOLUTION	
	Identification number:	-		



Page 2 of 16

Trading name:	PICRIC ACID IN ACETONE, SOLUTION				
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4

	Authorization number:	-
	Hazard pictograms:	GHS02 GHS07
	Signal word:	Danger
	Hazard statements:	 H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. EUH066 Repeated exposure may cause skin dryness or cracking.
	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. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. 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	
	-	

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)	
67-64-1/ 200-662-2/ 606-001-00-8	-	≥ 50 % - < 100 %	acetone	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 EUH066	
88-89-1/ 201-865-9/ 609-009-00-X	-	< 0.1 %	picric acid	Expl. 1.1; H201 Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331	

SECTION 4. First aid measures		
4.1	Description of first aid measures	



Page 3 of 16

Trading name:	PICRIC ACID IN ACETONE, SOLUTION				
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4

	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:	Do not induce vomiting. Do not insert any object into the unconscious person's mouth. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and ef	fects, both acute and delayed
	Following inhalation:	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 medi	cal attention and special treatment needed
	-	

SECTIO	SECTION 5. Firefighting measures					
5.1	Extinguishing media					
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol resistant foam				
	Unsuitable extinguishing media: No information available.					
5.2	Special hazards arising from the su	ibstance or mixture				
	Hazardous combustion products:	Carbon monoxide (CO).				
5.3	Advice for firefighters					
	Use a self-contained open-circuit o	compressed air breathing apparatus and fireproof clothing.				
5.4	Additional information					
	Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.					



Page 4 of 16

Trading name:	PICRIC ACID IN ACETONE, SOLUTION				
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4

SECTIO	ON 6. Accidental release measu	ures				
6.1	Personal precautions, protective equipment and emergency procedures					
6.1.1.	For non-emergency personnel					
	Protective equipment:	Use personal protective equipment (see Section 8).				
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.				
	Emergency procedures:	Mark the area using proper signs.				
6.1.2.	For emergency responders:					
	Use protective equipment; in c (see Section 8).	ase of inadequate ventilation use adequate airways protective equipment				
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 cont	ainment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.				
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.				
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).				
6.4	Reference to other sections					
	See Section 7 for information of	on safe handling.				
		on personal protection equipment.				
	See Section 13 for disposal info	ormation.				

SECTIO	SECTION 7. Handling and storage					
7.1	Precautions for safe handling					
7.1.1.	Protection measures					
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.				
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.				



Page 5 of 16

Trading name:	PICRIC ACID IN ACETONE, SOLUTION				
Product code:	РКА-ОТ-Х**	Revision date:	04 July 2019	Version:	4

	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 wash hands after work and before eating.		
7.2	Conditions for safe storage, including any incom	npatibilities		
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.		
	Packaging materials:	Manufacturer's original packaging. Unsuitable material for receptacle: aluminium.		
	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:	-		

SECTIO	SECTION 8. Exposure controls/personal protection							
8.1	Control pa	arameters	ameters					
Substance		CAS No			Occupational exposure limit values/short term values		Biological limit values	
					рр	m	mg/m ³	
Acetone	5		67-	-64-1	50	0	1210	-
Substan	ce name:	-						
EC No:		-	CAS No	:	-			
DNEL								
Industrial								
Route o	of	Acu	Acute Acute Chronic Chronic					
exposu	re:	effect	local	effe	effect systemic		effect local	effect systemic
Oral		-		-		-		-



Page 6 of 16

						Page 6 of 16
Trading			PICRIC	ACID IN A	CETONE, SOLUTI	
Product	code:	PKA-OT-X**	Revisi	on date:	04 July 2019	Version: 4
.						1210 (3(
Inhalatior Dermal	<u>ו</u>	-	-	-		1210 mg/m ³ (acetone)
	· .					186 mg/kg (acetone)
Critical pi	nysical para	ameters: solubility,	-		-	
				onsumer		
	Route of Acute Acute				Chronic	Chronic
exposure		effect local	effect system		effect local	effect systemic
Oral Inhalatior		-	-	-	g/m ³ (acetone)	-
Dermal	1	-	-		g/m (acetone) g/kg (acetone)	-
PNEC				02 110	y kg (acetone)	
	ontal prot	action target		PNEC		
Fresh wat	•	ection target			(
				10.6 mg/l		
	er sedimen	Its		-	g (acetone)	
Marine w				1.06 mg/l (acetone)		
Marine se				3.04 mg/kg (acetone)		
Food cha				no information available		
-		sewage treatment		100 mg/l (acetone)		
Soil (agrio	cultural)			29.5 mg/k	g (acetone)	
Air				no inform	ation available	
8.2		re controls				
8.2.1.	Approp	priate engineering	controls	1		
	Substa	nce/mixture related	d measures to			ated rooms. Use personal
	preven	t exposure during	identified uses:	protective equipment. Do not eat, drink or smoke in the workspace.		
	Structu	ral measures to pr	event	•		
	exposu	•		In accordance with Section 7.		
	Organi	sational measures	to prevent	Organization of work in order to reduce other worker's		
	exposu	re:		influence during work process.		
		Technical measures to prevent exposure:Secure proper workspace ventilation in order to kee concentration levels in air below permitted levels. Se stations for rinsing eyes and showering.			•	-
	Technio				-	
8.2.2.	Person	al protection equip	oment			
			Safety	glasses that	t stick to face (EN 16	56) or visor in case of lower
8.2.2.1.	Eye and	d face protection:			•	ve gas mask that covers the
			entire	tace in case	of higher levels of o	concentration in air.
8.2.2.2.	Skin pr	otection				



Page 7 of 16

Trading name:			PICRIC ACID IN ACETONE, SOLUTION						
Product code:		PKA-OT-X** Revision date: 04 July 2019 Version:							
	Hand protection:		The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Full contact: Glove material: butyl rubber Glove thickness: ≥ 0.50 mm Time until perforation: > 480 min Splash contact: Glove material: nitrile rubber Glove thickness: 0.4 mm Break through time: 35 min						
	Other	skin protection:	During everyday work use antistatic clothing (EN 13688) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.						
8.2.2.3.	Respir	atory protection:	inadequate ventila	n level exceeds the GVI tion), use a filter for org C) according to EN 143	anic vapors, type "A				
8.2.2.4.	Therm	al hazards:	No information available						
8.2.3.	Enviro	nmental exposure controls							
		ance/mixture related ires to prevent exposure:	See Section 6						
		uctural measures to prevent osure: Use modern equipment.							
		isational measures to nt exposure:	Adapt the work process to the required working conditions of the workplace.						
	Techn expos	ical measures to prevent ure:	See Section 6						

SECTI	SECTION 9. Physical and chemical properties					
9.1	Information on basic physical and chemical properties					
		Value	Method			
	Physical state:	liquid	No information available			
	Colour:	colourless	No information available			
	Odour:	acetone like	No information available			
	Odor threshold:	No information available	No information available			
	pH:	No information available	No information available			
	Melting point / freezing point;	No information available	No information available			



Page 8 of 16

Trading name:		PICRIC ACID IN A	CETONE, SOLUTION		
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4

	Initial boiling point and boiling range:	56 °C	No information available
	Flash point:	< 0 °C	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n- octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
	-		

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

SECTION 11. Toxicological information								
11.1	Information on toxicological effects							
	Acute toxicity:							
Route o exposur		Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results		
Oral:		-	rat (acetone)	LD ₅₀	-	>2,000 mg/kg		



Page 9 of 16

						Page	9 of 16
Trading name:		PIC	RIC ACID IN A	ACETONE, SO	LUTION		
Product code:	PKA-OT-X**	R	evision date:	04 July 20	019	Versi	on: 4
Dermal:	_	rat (aceton	a) II	D ₅₀	_		2,000 mg/kg
Inhalation:	_	rat (aceton)		C ₅₀	4 h		2,000 mg/kg 20 mg/l
		Tat (acetoni	e) L	C ₅₀	4 11		20 mg/i
Specific	target organ toxici	ty – single exp	osure (STOT SE):			
	Spec	cific effects		Target organ	l	Ν	lote
Oral:	No information	n available	No inf	ormation availa	ble	-	
Dermal:	No information	n available	No inf	ormation availa	ıble	-	
Inhalation:	No information	n available	No inf	ormation availa		may cause or dizzines	e drowsiness ss
Aspirati	on hazard:	1	No information	available.			
Irritatio	n and corrosion					1	
	Exposu	re time	Species	Evaluation	Method		Note
Skin corrosion/irritati	on:	-		-	-	-	
Serious eye damage/irritatio	n -	-		-	-	causes s irritation	serious eye n
Sensitiz	ation						
Skin sensitization	n: No in	formation ava	ilable.				
Respiratory sens	itization: No in	formation ava	ilable.				
Sympto	ms related to the p	hysical chemi	cal and toxicolo	gical characteri	stics		
Oral exposure:	•	ion available.		gical characteri.			
Dermal exposure		ion available.					
Inhalation expos		ion available.					
Eye exposure:		ion available.					
<u> </u>	i						
Repeate	ed dose toxicity (sul	pacute, subchr	onic, chronic)				
	Dose	Exposure time	Species	Method	Evaluat	ion N	lote
Subacute oral	No information available	No information available	No information available	No information available	No informa availab		
Subacute dermal	No information available	No information available	No information available	No information available	No informa availab		



Page 10 of 16

Trading name:		PICRIC ACID IN A	CETONE, SOLUTION		
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4

Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	_
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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

CMR effects (carcinogenicity; mutagenicity; reproduct	uctive toxicity)
---	------------------

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 available data, the classification criteria are not met.
Mutagenicity in vivo:	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.



Page 11 of 16

						Fage II OF IG	<u> </u>		
Tradir	ng name:		PICRIC		CETONE, SOLUTION				
Product code:		PKA-OT-X**	Revis	ion date:	04 July 2019	Version:	4		
	Reproduc	ctive toxicity:	Ва	ised on availa	ble data, the classificati	on criteria are not i	net.		
	Summary of evaluation of the properties:		the CMR	CMR Based on available data, the classification criteria are no met.					
11.2	Practical	experiences:							
	Classification observations:			No information available					
	Other ob	servations:		No information available					
11.3	General r	notes:							
	-								

12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	fish	No information available	>1,000 mg/l (acetone)	-
Crustacea:	EC ₅₀	48 hours	Daphnia magna	No information available	>1,000 mg/l (acetone))	-
Algae/aquatic plants	IC ₅₀	4 days	algae	No information available	>1,000 mg/l (acetone))	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
	-	_	_	_	_	_



Page 12 of 16

Trading name:		PICRIC ACID IN A	CETONE, SOLUTION		
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4
	legradation				

Abioti	c degrada	tion		1					
	Degra	adation half-	lives	N	1ethod	Evaluatio	n		Note
Marine water	water No information available		No info availat	ormation ole	No information available	n -			
Fresh water	er No information available		lable	No info availat	ormation ble	No information available	n -		
Air	No information available		No info availat	ormation ble	No information available	n -			
Soil	No info	rmation avai	lable	No info availat	ormation ole	No information available	n -		
Bioder	gradation								
% Degradation	-	Time (day	s)	N	lethod	Evaluatio	n		Note
No information available	n No		mation		ormation	No information available	n N	No info availabl	rmation
		e potential partition coef	ficient (log Kow)				
Value	Concenti	ration	рН	°C	Method	Evalu	ation		Note
		-		-	-	-		-	
Biocor	ncentratio	n factor (BCF	-)						
Value		Species			Method	Evaluati	on		Note
No information available			No information available		No information available		-		
Chron	ic ecotoxi	city			:		÷		
Value Lose ·		osure ime	Species	Method	Evaluat	tion	Note		
Chronic toxicity on fish LC ₅₀ i		No infor availa	mation	No information available	No information	No informat available		-	



Page 13 of 16

									Page 13 of 1	0
Trading name:				PICRIC ACID IN ACETONE, SOLUTION						
Produc	Product code: PKA-OT-X**		A-OT-X**	Revisi	:: 04 Ju	uly 2019		Version:	4	
Chronic crustace	-		EC ₅₀	information	No informa available		ation ir	lo nformation vailable	-	
12.4	Mobili	ty in soi								
	Knowr	or prec	licted distributi	on in environme	ental con	npartments:				
	No inf	ormatio	n available							
	Surface	e tensio	n:	1				T		
	Va	lue	°C	Concentrat	ion	Metho	bd		Note	
	No inform availab		No information available	No informati available		lo informatio vailable	n	-		
	Adsorp	otion / d	lesorption							
Transpo	ort	-	coefficient 's constant	log Kow Evaporat		oration rate	on rate Method		Note	
Soil-wat	tor	lo vailable	information	No information No informavailable available		nformation able	available		-	
Water-a	air	lo vailable	information	No information available		No information No ir available availa		rmation le	-	
Soil-air		lo vailable	information	No information available			No info availabl	rmation e	-	
12.5	Results	s of PBT	and vPvB asses	sment						
	Not ap	plicable	<u>.</u>							
12.6	Other	adverse	effects							
			evant information	on available.						
SECTIO	N 13. D	isposal	consideration	s						
13.1	Wast	te treatn	nent methods							
13.1.1.	Prod	uct/Pac	kaging disposa	:						
	Subr Prote		isposal to the le	egal person auth	norized k	y the Ministr	y of Envir	onmental a	and Nature	

SAFETY DATA SHEFT

					Page 14 of 1	6
Trading	name:		PICRIC ACID IN A	CETONE, SOLUTION	[
Product	code:	РКА-ОТ-Х**	Revision date:	04 July 2019	Version:	4
13.1.2.	Waste (odes/waste designativ	ons according to Law:			
19.1.2.	Waste codes/waste designations according to Law: Packaging that contains residual hazardous substances or is contaminated with hazardous substances					
	Таскау					ices
13.1.3.	Waste treatment – relevant information:					
	No information available					
	1					
13.1.4.	Sewage	e disposal – relevant in	formation:			
	Waste r	nust not be disposed	of into the sewage system.			
13.1.5.	Other d	lisposal recommendat	ions:			
	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.	Relevan	nt Community provisio	ns:			
	Disposa	al must be made accor	ding to official regulations			
SECTION	N 14 TRAI	NSPORT INFORMATI	ON			
	Transport	ting/shipment by road	(ADR)			

Transporting/shipment by	road (ADR)
UN number:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	П
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by	rail (RID)
UN number:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	Ш
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport	(ADN)
UN number:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	Ш
Environmentally hazardous:	-



Page 15 of 16

Trading name:	I	PICRIC ACID IN ACE	TONE, SOLUTION		
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4

Special precautions for user:	-
Transporting/shipment by sea (IN	MDG)
UN number:	1090
UN proper shipping name:	Acetone
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:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	Ш
Environmentally hazardous:	-
Special precautions for user:	-
Further information: -	

SECTIO	ECTION 15. Regulatory information				
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorization and/or restr	rictions of use			
	Authorizations:	-			
	Restrictions:	-			
		EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;			
	Other EU regulations:	Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);			
		EC Regulation No. 2037/200 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;			
		EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;			
		EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;			
		Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives			



Page 16 of 16

Trading name:	PICRIC ACID IN ACETONE, SOLUTION				
Product code:	PKA-OT-X**	Revision date:	04 July 2019	Version:	4

	Information according 19 guideline)	999/13/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 assessm	ent
	None	

SECTIC	CTION 16. Other information					
16.1	Indi	cation of changes:	-			
			PBT Stable, bioaccumulative and toxic			
			vPvB Strongly stable and strongly bioaccumulative.			
16.2	Abb	previations and acronyms:	LD ₅₀ Lethal dose, 50%			
			LC ₅₀ Lethal concentration, 50%			
			TCOJ Specific target organ toxicity - single exposure			
16.3.	-	literature references and rce of data:	-			
16.4.		ssification and procedure 2/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)			
Classifi	catior	ו	Classification procedure			
-			-			
16.5.	Rele	evant H statements (num	per and full text)			
	H:	H201	Explosive; mass explosion hazard.			
		H225	Highly flammable liquid and vapor.			
		H301+H311+H331	Toxic if swallowed, in contact with skin and if inhaled.			
		H319	Causes serious eye irritation.			
		H336	May cause drowsiness or dizziness.			
16.6.	Trai	ning advice:	-			
	6.7. Further information:		** "X" in the product code marks different volumes (different packagings of the product)			
16.7.			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