

SUDAN BLACK B KIT

The kit contains:

Acetone for histology Glutaraldehyde, 4% buffered solution Hematoxylin G3 Sudan Black B reagent



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

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Trading name:	ACETONE FOR HISTOLOGY				
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

1.1	Product identifier					
	Trading name:	ACETONE F	OR HISTO	DLOGY		
	Chemical name:	propanone				
	Catalogue number:	AC-X**				
1.2	Relevant identified us	es of the subs	tance or n	nixture and uses advised against		
	Uses:		For use	with special staining kits.		
	Uses advised against:		Only the	e identified uses are advised.		
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.			
1.3	Details of the supplier of the safety data sheet					
	Supplier:		BioGnost Ltd.			
	Address:	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997			
	Telefax.:		+385 1 2404039			
	e-mail of competent	person:	msds@biognost.hr			
	National contact:		-			
1.4	Emergency telephone	Emergency telephone number				
	National Protection a	nd Rescue Dire	ectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:					

SECTIO	CTION 2. Hazards identification			
2.1	Classification of the substance or mixture			
2.1.1	Classification according to Regulation (EC) No	o 1272/2008 (CLP)		
	Hazard class and category code:	Hazard statements*:		
	Flam. Liq. 2	H225		
	Eye Irr. 2	H319		
	STOT SE 3	H336		
		EUH066		
2.1.2.	Additional information			
	-			
*For fu	III text of Hazard- and EU Hazard-statements: se	ee SECTION 16		
2.2	Label elements			
	Product identification: ACETONE FC	DR HISTOLOGY		



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	Identification number:	_
	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.
	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. P308 + P313 IF exposed or concerned: Get medical advice/attention.
	Supplemetal hazard information (EU):	EUH066 Repeated exposure may cause skin dryness or cracking.
2.3	Other hazards	
	-	

SECTION 3. Cor	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	-	100 %	acetone	Flam. Liq. 2; H225 Eye Irr. 2; H319 STOT SE 3; H336 EUH066			

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.			



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	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
2	<u> </u>	

SECTIO	CTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO2 Large fire - water spray or alcohol resistant foam			
	Unsuitable extinguishing media:	No information available			
5.2	Special hazards arising from the su	ubstance or mixture			
	Hazardous combustion products:	Carbon monoxide (CO)			
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				
	Do not contaminate the environment	ent with extinguishing media.			



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SECTIO	ON 6. Accidental release meas	ıres	
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 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 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	
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).	
6.4	Reference to other sections		
	See Section 7 for information of	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. 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.		



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1				
	Other measures:	-		
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.		
	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. Expos	ure contr	ols/perso	nal protec	tion				
8.1 Control p	Control parameters							
Substance	9	CA	S No			exposure limit term values	E	Biological limit values
				рр	m	mg/m³		
Acetone		67	7-64-1	50	0	1210	No	o information available
Substance name:	-							
EC No:	-	CAS No	-					
DNEL								
				Indus	trial			
Route of	Acı	ıte	Acut	te		Chronic		Chronic
exposure:	effect	local	effect sys	stemic		effect local		effect systemic
Oral	-		-		-		-	
Inhalation	-		-		-			1210 mg/m³ (acetone)
Dermal	-	_	-	•	-	-		186 mg/kg (acetone)



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rioduct		AC-X	Dute 01		impliation: 14 Septem	ibei 2022 Version. 1
Critical ph	nysical par	ameters: solubility,	flammability, co	rros	sivity: -	
	· · ·		<u> </u>		ımer	
Route of		Acute	Acute		Chronic	Chronic
exposure):	effect local	effect systemi	ic	effect local	effect systemic
Oral		-	-		-	-
Inhalation	1	-	-		200 mg/m3 (acetone)	-
Dermal		-	-		62 mg/kg (acetone)	-
PNEC						
Environm	ental prot	ection target		PI	NEC	
Fresh wat	er			1	10.6 mg/l (acetone)	
Freshwate	er sedimer	nts		3	30.4 mg/kg (acetone)	
Marine wa	ater			1	1.06 mg/l (acetone)	
Marine se	diments			3	3.04 mg/kg (acetone)	
Food chai	in			١	No information available	
Microorga	anisms in	sewage treatment		100 mg/l (acetone)		
Soil (agric	cultural)			29.5 mg/kg (acetone)		
Air				No information available		
8.2	Exposu	ire controls				
8.2.1.	Appro	priate engineering o	controls			
		nce/mixture related It exposure during i		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.		
	Structı exposı	ıral measures to pre ıre:	event	In accordance with Section 7.		
	Organi expost	sational measures t ire:	to prevent	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.		low permitted levels. Secure	
8.2.2.	Person	al protection equip	ment			
8.2.2.1.	Eye an	d face protection:	Safety glasses that stick to face (EN 166) or visor in case of levels of concentration in air; protective gas mask that concentre face in case of higher levels of concentration in air.		ve gas mask that covers the	
8.2.2.2.	Skin pı	otection	L			



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	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 rubberGlove thickness: ≥ 0.50 mm Time until perforation: > 480 minSplash contact: Glove material: nitrile rubber Glove thickness: 0.4 mm Break through time: 35 min
	Other skin protection:	During every day 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.	Respiratory protection:	If the concentration level exceeds the GVI values (or because ofinadequate ventilation), use a filter for organic vapors, type "A"(boiling point >65°C) according to EN 14387.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTI	SECTION 9. Physical and chemical properties				
9.1	Information on basic physical and chemical properties				
		Value	Method		
	Physical state:	liquid	Visual inspection		
	Color:	colourless	Visual inspection		
	Odour/odour threshold:	acetone like/no information available	No information available		
	Melting point / freezing point:	-94.7 °C	No information available		



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	Boiling point or initial boiling point and boiling range:	56.1 °C	No information available
	Flammability:	Highly flammable	No information available
	Lower and upper explosion limit:	2.5 vol % 14.3 vol %	No information available
	Flash point:	-17 °C	No information available
	Auto-ignition temperature:	465 °C	No information available
	Decomposition temperature:	No information available	No information available
	рН:	No information available	No information available
	Kinematic viscosity:	Dynamic 0.32 mPas (at 20°C)	No information available
	Solubility:	with water fully miscible	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	240 hPa	No information available
	Density and/or relative density	0.79 g/cm³ at 20 °C	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
	Physical state:	No information available	No information available
.2	Other information		
	-		

SECTION	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 of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results				



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Oral:	-	_ rat		LD ₅₀		-		>2,000 m (aceto	
Dermal:	-	rat		LD ₅₀		-		>2,000 m (aceto	
Inhalation:	-	rat		LD ₅₀		4 h		20 mg (acetor	
Specific ta	rget organ tox	icity – single ex	posure (S	TOT SE):					
į '	 	ecific effects			Target orga	an		Note	
Oral:	No informati			No infor	mation avai		_		
Dermal:	No informati	on available			mation ava		-		
Inhalation:	No informati				mation ava	may caus		ause drowsi ziness	ness
Aspiration	hazard:		No inform	mation av	ailable.				
Irritation a	and corrosion								
	Expo	sure time	Spec	ies	Evaluation	Method		Note	
Skin corrosion/irritation	- ·		-	-	-	-	-		
Serious eye damage/irritation	-		-	-	-	-		ses serious (ation	eye
ì									
Sensitizati	on								
Skin sensitization:	-								
Respiratory sensitiz	zation: -								
i									
Symptoms		physical, chem		oxicologi	cal characte	ristics			
Oral exposure:	No inform	ation available	•						
Dermal exposure:	No inform	ation available	•						
Inhalation exposure	e: No inform	ation available	•						
Eye exposure:	No inform	ation available	•						
Reneated	dose toxicity (s	subacute, subch	ronic ch	ronic)					
Nepeated	Dose Dose	Exposure time	Specie		Method	Evalua	ition	Note	



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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 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	_



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	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 <i>in vivo</i> :	Based on available data, the classification criteria are not met.
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
	Reproductive toxicity:	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.
1.2.	Information on other hazards:	
1.2.1.	Endocrine disrupting properties:	
	No known endocrine disrupting properties that affect human health.	
1.2.2.	Other information:	

SECTION 12. Ecological information								
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	8 days	algae	No information available	>1,000 mg/l (acetone)	-		
Other organisms	-	72 hours	-	-	-	-		
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		



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

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

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

12.3 Bioaccumulative potential										
Octanol-water partition coefficient (log Kow)										
Value	Concentration	рН	°C	Method	Evaluation	Note				
-	No information available	-	-	No information available	No information available	-				



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	Biocor	ncentrati	on factor (BCF)									
V	/alue		Species		М	ethod		E۱	/aluatio	on .		Note
No info	ormation le		•	ation	No infor		n	No info		on	No inf	ormation ole
	Chroni	ic ecoto	kicity									
	Value	e	Dose		osure ime	Spe	cies	Meth	nod	Eval	uation	Note
Chronic	c toxicity	y on fish	LC ₅₀	No infor availa		No inforn availa		No informavailab		No inform availab		-
	c toxicity ea (<i>Dapl</i>		EC ₅₀	No infor availa	mation	No inform availa		No informavailab		No inform availab		-
12.4	Mobili	ity in soi										
	Knowr	n or prec	licted distributi	on in e	environme	ental co	ompart	ments:				
	No inf	formatio	n available									
	Surfac	e tensio	n:									
	Va	lue	°C	C	oncentrat	ion		Metho	od			Note
	No inform availab		No information available		informati ilable	on	No inf availat	ormation ole	n	-		
	Adsor	ption / d	esorption									
Transpo	•	A/D o	coefficient 's constant	lc	og Kow	Ev	aporati	on rate		Method		Note
Soil-wa	ıt∆r :	No available	information	No ir	nformation able	_	inform ailable	nation	No ir	nformati able	on _	
	u			Ĭ				. •	No ir	nformati	on	
Water-	air N	No available	information	No ir availa	nformation able		inform ailable	nation	availa		-	



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	Based on available data, the product does not contain any PBT or vPvB substances.
	Table of a tallance added, the product does not contain any 121 of 1112 substances.
12.6.	Endocrine disrupting properties
	No known endocrine disrupting properties that affect the environment.
12.7.	Other adverse effects
	No information available
SECTIO	N 13. Disposal considerations
13.1	Waste treatment methods
13.1	waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
13.1.1.	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	N 14 TRANSPORT INFORMATION
	Transporting/shipment by road (ADR)



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UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (R	ID)
UN number:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	II
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:	II
Environmentally hazardous:	-
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:	II
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 (ICA	AO-TI/IATA-DGR)
UN number:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-



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Trading name:					
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

15.1	ON 15. Regulatory information Safety, health and environment	nmental regulations/legislation specific for the substance or mixture					
13.1	EU regulations						
	Authorization and/or rest	rictions of use					
	Authorizations:	-					
	Restrictions:	-					
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);					
	Information according 19 quideline)	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:	-



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

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Trading name:	ACETONE FOR HISTOLOGY					
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7	

16.2	Abk	previations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative		
16.3.	Key literature references and source of data:				
16.4.		ssification and procedure 2/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)		
Classifi	catior	١	Classification procedure		
_			-		
16.5.	Rele	evant H statements (numb	er and full text)		
		225	Highly flammable liquid and vapor.		
	H:	319	Causes serious eye irritation.		
		336	May cause drowsiness or dizziness.		
		EUH066	Repeated exposure may cause skin dryness or cracking.		
16.6.	Trai	ning advice:	-		
16.7.	Fur	ther information:	-		

ANNEX: Exposure scenario resulting to chemical safety assessment
-



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION						
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4		

SECTI	ON 1: Identification of	the substan	ce/mixture an	d of the company/undertaking		
1.1.	Product identifier					
	Trade name:	GLUTARA	LDEHYDE, 4% E	BUFFERED SOLUTION		
	Chemical name:	-				
	Catalogue number:	G4-OT-X*	*			
1.2.	Relevant identified us	es of the sub	stance or mixt	ure and uses advised against		
	Uses:		For use with S	Sudan Black B kit.		
	Uses advised against:		Only the iden	tified uses are advised		
	Reason why uses advi against:	sed	The product is intended for use only as an <i>in vitro</i> diagnostic medical device and there is no reason to use it for other purposes			
1.3.	Details of the supplier	of the safet	y data sheet			
	Supplier:		BioGnost Ltd.			
	Address:		Medjugorska 59, Zagreb			
	Telephone number:		+385 1 2409997			
	Telefax:		+385 1 24040	039		
	e-mail of competent բ	person:	msds@biognost.hr			
	National contact:		-			
1.4.	Emergency telephone	numbers				
	National Protection ar	nd Rescue D	irectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:		_	-		

SECTIO	ON 2. HAZARDS IDENTIFICATIO	N			
2.1.	Classification of the substance	or mixture			
2.1.1.	Classification according to Reg	ulation (EC) No 12	72/2008 (CLP)		
	Hazard class and categ	ory code:	Hazard statement*:		
	Acute Tox. 4		H302		
	Skin Sens. 1		H317		
	Acute Tox. 4		H332		
	Resp. Sens. 1		H334		
2.1.2.	Additional information				
	-				
* For fu	ull text of Hazard- and EU Hazard	-statements: see S	ECTION 16		
2.2.	Label elements				
	Product identification:	GLUTARALDEH	YDE, 4% BUFFERED SOLUTION		
	Identification number:	-			



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION					
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

	Authorisation number:	-
	Hazard pictograms:	GHS07 GHS08
	Signal word:	Danger
	Hazard statement:	H302 Harmful if swallowed.H317 May cause an allergic skin reaction.H332 Harmful if inhaled.H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
		ns no components considered to be either persistent, bioaccumulative and and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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)			
111-30-8/ 203-856-5/ 605-022-00-X	-	4- 5 %	glutaraldehyde	Acute. Tox. 3; H331 Acute Tox. 3; H301 Skin Corr. 1B; H314 Resp. Sens. 1; H334 Skin Sens. 1; H317 Aquatic Acute 1; H400			

SECTION 4. First aid measures



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION					
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

4.1.	Description of first aid meas	ures				
	General notes:	Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident. Immediately remove any clothing soiled by the product.				
	Following inhalation:	Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness place patient stably in side position for transportation.				
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap and rinse thoroughly. If symptoms persist, consult a doctor.				
	Following eye contact: Rinse opened eye for several minutes under running water. If sympto persist, consult a doctor.					
	Following ingestion:	DO NOT induce vomiting. If symptoms persist, consult a doctor.				
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.				
4.2.	Most important symptoms a	Most important symptoms and effects, both acute and delayed				
	Following inhalation:	High concentration vapor inhalation may cause headache, dizziness, difficult breathing and unconsciousness.				
	Following skin contact:	Causes skin irritation, redness, swelling. Prolonged or repeated contact causes defatting and dry skin.				
	Following eye contact:	Vapors irritate eyes. Splashing may cause irritation and redness.				
	Following ingestion:	Nausea, vomiting (danger of aspiration), diarrhoea. Aspiration may cause headache, vertigo, nausea, dazed feeling-unconsciousness/coma, possible hypothermia, reactions to the heart/circulatory system such as vasodilation (flush), hypotension, arrhythmia (possible ventricular fibrillation through cardiac sensitization), danger of central respiratory paralysis or of cardiac arrest; functional disturbance to the liver and kidneys and persistent disturbance to the CNS as sequelae.				
4.3.	Indication of any immediate	medical attention and special treatment needed				
	No further relevant informat	tion available.				

SECTI	SECTION 5. Firefighting measures					
5.1.	Extinguishing media					
	Suitable extinguishing media:	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.				
	Unsuitable extinguishing media:	water with full jet				
5.2.	Special hazards arising from the sul	bstance or mixture				
	Hazardous by products of fire:	Formation of toxic gases is possible during heating or in case of fire.				
5.3.	Advice for firefighters					
	Use a self-contained open-circuit co	ompressed air breathing apparatus and fireproof clothing.				



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION						
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4		

5.4.	Additional information
	Collect contaminated firefighting water separately.
	Do not contaminate the environment with extinguishing media.

SECTIO	ON 6. Accidental release m	easures			
6.1.	Personal precautions, prot	ective equipm	nent and emergency procedures		
6.1.1.	For non-emergency perso	nnel			
	Protective equipment:		Use personal protective equipment (see Section 8). Keep unprotected persons away.		
	Accident prevention methods:		Evacuate members of all non-essential personnel and those members without protective equipment. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.		
	Emergency procedures:	N	Mark the area using proper signs.		
6.1.2.	For emergency responders:				
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).				
6.2.	Environmental precautions:				
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.				
6.3.	Methods and materials for	containment	and cleaning up		
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or cla	ay barriers.		
6.3.2.	Cleaning up:	Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and 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	e tools that may cause sparks.		
6.4.	Reference to other section	S			
	See Section 8 for informat	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.			

SI	SECTION 7. Handling and storage			
7.	1.	Precautions for safe handling		
7.	1.1.	Protection measures		



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION					
Product code:	G4-OT-X**	Date of compilation: 21 Dec 2022	Version:	4		

	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition. Carry out measures for preventing static electricity.			
	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 wash hands after work and before eating.			
7.2.	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.			
	Packaging materials:	Manufacturer's original packaging.			
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.			
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.			
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).			
7.3.	Specific end use(s)				
	Recommendations:	-			
	Industrial sector specific solutions:	-			

SECTION 8. I	SECTION 8. Exposure controls/personal protection								
8.1. Con	ol parameters								
Substance		CAS No		Occupational exposure limit values/short term values		Biological limit values			
				ppm	mg/m³				
Glutaraldehy	Glutaraldehyde			0.05/0.05	0.2/0.2	-			
Substance:	Substance: -								
EC No: - CAS No: -									
DNEL									



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION						
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4		

Product code:	ct code: G4-OT-X** Da		mpilation:	21 Dec 2022	Version:	4	
		li li	ndustrial				
Route of exposur	oute of exposure: Acute effect local		effect emic	Chronic effect local		nic effect stemic	
Oral	-	-		-	-		
Inhalation	-	-		-	-		
Dermal	-	-		-	-		
Critical physical p	parameters: solubility, fl	ammability, co	orrosivity:	-			
		C	onsumer	·			
Route of exposur	e: Acute effect local	Acute syste		Chronic effect local		nic effect stemic	
Oral	-	-		-	-		
Inhalation	-	-		-	-		
Dermal	-	-		-	-		
PNEC		<u> </u>					
Environmental pr	otection target		PNEC				
Fresh water			No information available				
Freshwater sedin	nents		No information available				
Marine water			No information available				
Marine sediment	S		No information available				
Food chain			No information available				
Microorganisms	in sewage treatment		No information available				
Soil (agricultural)			No information available				
Air			No information available				
8.2. Expo	osure controls						
8.2.1. App	ropriate engineering co	ontrols					
mea	measures to prevent exposure			Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
Structural measures to prevent exposure: Organisational measures to prevent exposure: Organization of work in order to reduce othe during work process.							
				ganization of work in order to reduce other worker's influence ring work process.			
	nnical measures to prevosure:			orkspace ventilation in els in air below permit	•		

Personal protection equipment:

8.2.2.



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Trade name:		GLUTARALDEHYDE, 4% BUFFERED SOLUTION						
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4			

8.2.2.1.	Eye and face protection:	Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU)		
8.2.2.2.	Skin protection			
		Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.		
		Full contact: Glove material: Viton		
	Hand protection:	Glove thickness: 0.7 mm		
		Break through time: 480 min		
		Splash contact:		
		Glove material: Nitrile rubber		
		Glove thickness: 0.4 mm		
		Break through time: 35 min		
	Other skin protection:	Complete suit protecting against chemicals, flame retardant antistatic protective clothing (EN 13688). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.		
8.2.2.3.	Respiratory protection:	Where risk assessment shows air-purifying respirators are appropriate use type ABEK (EN 14387) respirator cartridges as a backup to engine protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as CEN (EU).		
8.2.2.4.	Thermal hazards:	No information available		
8.2.3.	Environmental exposure controls			
	Substance/mixture related measures to prevent exposure:	See Section 6		
	Structural measures to prevent exposure:	Use modern equipment.		
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.		
	Technical measures to prevent exposure:	See Section 6		

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



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Trade name:		GLUTARALDEHYDE, 4% BUFFERED SOLUTION						
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4			

Colour:	colourless	No information available
Odour/odour threshold:	No information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
Flash point:	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
рН:	No information available	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density:	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
Other information		

SECTIO	ECTION 10.: Stability and reactivity					
10.1.	Reactivity:	No relevant information available.				
10.2.	Chemical stability:	The product is chemically stable under recommended storage conditions.				
10.3.	Possibility of hazardous reactions:	No dangerous reactions known.				
10.4.	Conditions to avoid:	Sources of heat, flamesa and sparks.				
10.5.	Incompatible materials:	Strong oxidizing agents.				
10.6.	Hazardous decomposition products:	Carbon monoxide.				

SECTIO	SECTION 11. Toxicological information										
11.1.	Informatio	Information on toxicological effects									
	Acute toxic	Acute toxicity:									
Route o		Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results					



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Trade name:			GLU	TARALDE	HYDE,	4% BUFF	ERED SOLU	JTION	
Product code:	G4-OT-X	DT-X** Date of compilati			lation:	21 Dec	2022	Versi	ion: 4
Oral:	No inforr	mation	_		No in availa	formation ble	No inform	nation	-
Dermal: No information available		mation	<u>-</u>					nation	-
Inhalation: No informati available		mation	-		No in availa	formation ble	No inform available	nation	-
Specific t	arget organ	toxicity - :	single	exposure (STOT-SI	≣):			
; •		Specific		•			t organ		Note
Oral:	No inforr	mation ava	ailable	!	No	o informati	on available	-	
Dermal:	No inforn	nation ava	ailable		No	o informati	on available	-	
Inhalation:	No inforr	nation ava	ailable		No	o informati	on available	-	
Aspiratio	n hazard:			-					
Irritation	and corrosic	on							
		Exposu time		Species	E	/aluation	Method		Note
Skin corrosion/irri	tation	-	-		-			No information available	
Serious eye damage/irritation		-				No information available			
Sensitizat	tion								
Skin sensitization:		nformation	n avail	lable					
Respiratory sensitization:		nformation							
SCHSIUZATION.									
Symptom	ns related to	physical,	chemi	cal, and tox	icologic	al properti	es		
Oral exposure:	nausea, c heart/circ ventricula of cardia	lazed feeli culatory sy ar fibrillation	ng-ur stem on thr	nconsciousn such as vas ough cardia	ess/cor odilatio ac sensi	na, possible n (flush), hy tization), da	e hypotherm ypotension, a anger of cent	ia, react arrhythr tral resp	neadache, vertigo, tions to the mia (possible piratory paralysis or stent disturbance to
Dermal exposure:	Causes sk dry skin.	kin irritatio	on, rec	iness, swelli	ng. Pro	onged or r	epeated con	tact cau	uses defatting and
Inhalation exposure:	breathing	g and suffo	ocatin	g. High con	centrati	on vapor ii		y cause	oat, cough, difficult headache, malaise orders.



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Trade name:		GLUTARALDEHYDE, 4	4% BUFFERED SOLU	TION	
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Eye exposure:		e eyes. Splashing , photophobia.	may cause irı	ritation and redne	ss, lacrimatio	on, pain, swelling,
Repeate	ed dose toxicity (su	ıbacute, subchro	onic. chronic)			
13P 3333	Dose	Exposure time	Species	Method	Evaluation	n Note
Subacute oral	No information available	No information available	No information available	No information available	No information	on -
Subacute dermal	No information available	No information available	No information available	No information available	No information available	on -
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	on -
Subchronic oral	No information available	No information available	No information available	No information available	No information available	on -
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	on -
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	on -
Chronic oral	No information available	No information available	No information available	No information available	No information available	on -
Chronic dermal	No information available	No information available	No information available	No information available	No information available	on -
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	on -
Coocitic	target ergan tavis	rity ropested s	vnocure (CTO	T DE).		
Specific	target organ toxio	Specific e	•	Target or	gan	Note
Subacute oral		No information		No information a		-
Subacute dermal		No information		No information a		_
Subacute inhalat		No information		No information a		-
Subchronic oral		No information	available	No information a	available	-



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Trade name:		GLUTARALDEHYDE, 4	1% BUFFERED SOLU	TION	
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Subchro	onic dermal	No information	n available	No information available	-		
Subchro	onic inhalation	No information	n available	No information available	-		
Chronic	oral	No information	n available	No information available	-		
Chronic dermal No information			n available	No information available	-		
Chronic inhalation No information		n available	No information available	-			
	CMR effects (carcinoger	icity, mutagenici	ty, reproduct	ive toxicity)			
	Carcinogenicity:			tion available			
	Mutagenicity in-vitro:		No informa	tion available			
	Genotoxicity:		No information available				
	Mutagenicity in-vivo:		No information available				
	Germ cell mutagenicity		No information available				
	Reproductive toxicity:		No information available				
	Summary of evaluatio properties:	n of the CMR	No informa	tion available			
11.2.	Information on other ha	zards:					
11.2.1.	Endocrine disrupting pro	operties:					
	No known endocrine that affect human health		erties				
11.2.2.	Other information:						
	_						

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	No information available	No information available	-	-				
Algae/aquatic plants:	IC ₅₀	72 hours	No information available	No information available	_	-				
Other organisms:	-	-	-	-	-	-				



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Trade name:		GLUTARALDEHYDE, 4% BUF	FERED SOLU	TION	
Product code:	G4-OT-X**	Date of compilation: 21 De	c 2022	Version:	4

Chronic (long-term) toxicity	Doza	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:	-	-	-	-	-	-

12.2. Pe	Persistence and degradability									
Ak	piotic degradation									
	Degradation half-lives	Method	Evaluation	Note						
Marine water	No information available	No information available	No information available	-						
Fresh wate	No information available	No information available	No information available	-						
Air	No information available	No information available	No information available	-						
Soil	No information available	No information available	No information available	-						

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

12.3. Bio	paccumulative potentia	al				
Oc	tanol-water partition o	oefficien	t (log Ko	ow)		
Value	Concentration	рН	°C	Method	Evaluation	Note
-	No information available	_	-	No information available	No information available	-
			<u> </u>			

Bioconcentration Factor (BCF)



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Value	<u> </u>		Species		N	1ethod	Ev	/aluation		Not	е
No informa available	ation	No infor			No info availabl	rmation e	No info	ormation ble	-		
Ch	nronic ed	cotoxicity									
V	/alue		Dose		posure time	Species	ľ	Method	Evalı	uation	Note
Chronic tox	xicity on	fish	LC ₅₀	No infor availa	mation able	No informatio available	1	ormation ilable	No inform availab		-
Chronic tox crustacea ([-		EC ₅₀	No infor availa	mation able	No informatio available		ormation ilable	No inform availab		-
Kn				ution in e	environmo	ental compar	tments:				
Kn No	nown or o inform urface te	predicted ation avai nsion:			environm						
Kn Nc Su Nc	nown or o inform urface te	predicted ation avai	ilable on No	°C	environmo rmation	ental compar Concent No informat available	ration	No info	Method rmation a		Note -
Kn Nc Su Nc	nown or o inform urface te	predicted lation avai nsion: alue	ilable on No	°C o infor		Concent No informat	ration	No info			
Kn Nc Su Nc ava	nown or o inform urface te Va o vailable	predicted lation avai nsion: alue information	on No	°C o infor		Concent No informat	ration	No info			
Kn Nc Su Nc ava	nown or or informurface tellows vailable dsorption	predicted lation avai nsion: alue informati	on No ave	°C o infor railable		Concent No informat	ration	No info	rmation a	available	
Kn Nc Su Nc ava	nown or or informurface tellows vailable dsorption	predicted lation avai nsion: alue information n / desorp D coefficienty's cons	on No ave	°C o infor railable	rmation g Kow nformatio	Concent No informat available Evaporat	ration ion		rmation a	available	-
No Su No ava	o informurface te	predicted nation avai nsion: alue information 'D coefficienty's cons informable informable informable	on No ave	°C o infor railable log No ir available	rmation g Kow nformatio e nformatio	Concent No informat available Evaporat n No informat available	ration ion ion rate mation	Metl No inforr	nod mation	available	-

12.5. Results of PBT and vPvB assessment



Trade name:

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

GLUTARALDEHYDE, 4% BUFFERED SOLUTION

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roauc	t code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4
			rains no components conside at and very bioaccumulative (v			nulative and
12.6.	Endocrin	e disrupting proper	rties			
	according	g to REACH Article	not contain components con 57(f) or Commission Delegate levels of 0.1% or higher.			
12.7.	Other ad	verse effects				
	No infor	mation available				
SECTIO	N 13 Disi	posal consideratio	ns			
13.1.		processing method				
13.1.1.		t/Packaging dispos	al: legal person authorized by t	he Ministry of Enviro	onmental and N	ature
	Protect	•				
13.1.2.	Waste	codes/waste desigr	nations according to Low:			
	Dispos	al must be made ac	cording to official regulation	S.		
13.1.3.	Waste	tretment – relevant	information			
	No info	ormation available				
13.1.4.	Sewage	e disposal – relevan	t information:			
			ed of into the sewage system	1.		
13.1.5.	Othor	disposal recommen	dations			
19.1.9.	Do not authorithe page	dispose of the pro- ized by the ministry	duct's remains into the sewag in charge. Do not dispose of ctors authorized by the minis	the packaging into	the sewage syst	em. Submi
13.1.6.		nt Community prov	isions:			
	-					
	N 14. Tra					



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by rail (R	ID)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland	waterways (ADN)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IN	MDG)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk condition in accordance with Annex II. of MARPOL 73/78 and IBC Codex:	-
Transporting/shipment by air (IC	AO-TI/IATA-DGR)
UN number:	3334
UN proper shipping name:	Aviation regulated liquid, n.o.s. (Glutaraldehyde)
Transport hazard class(es):	9
Packing group:	Ш
Environmental hazards:	-



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION					
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

Special precautions for user:	-
Further information: -	

SECTIO	ON 15. Regulatory informa	ation			
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorisation and/or rest	rictions on use			
	Authorisations:	-			
	Restrictions:	-			
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);			
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-			
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act			
15.2.	Chemical safety assessme	ent			
	None				

SECTION 16. Other information		
16.1. Indication of changes:	-	



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Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative			
16.3.	Key literature references and source of data:	-			
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)				
Classifi	cation	Classification procedure			
-		-			
16.5.	Relevant H statements (nu	mber and full text)			
	H301 H302 H314 H317 H331 H332 H334 H400	Toxic if swallowed. Harmful if swallowed. Causes severe skin burns and eye damage. May cause an allergic skin reaction. Toxic if inhaled. Harmful if inhaled May cause allergy or asthma symptoms or breathing difficulties if inhaled Very toxic to aquatic life.			
16.6.	Training advice:	-			
16.7.	Further information:	** "X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to Chemical safety assessment



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Trading name:	HEMATOXYLIN G3				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

SECTI	ON 1 IDENTIFICATION	OF THE SUBS	STANCE/MIX	TURE AND OF THE COMPANY/UNDERTAKING	
1.1.	Product identifier				
	Trading name:	HEMATOXYLIN G3			
	Chemical name:	-			
	Catalogue number:	HEMG3-OT-X**			
1.2.	Relevant identified use	s of the substance or mixture and uses advised against			
	Uses:		Hematoxylin according to Gill for nuclear staining.		
	Uses advised against: Reason why uses advised against:		Only the identified uses are advised.		
			The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes		
1.3.	Details of the supplier of the safety data sheet				
	Supplier:	: BioGnost Ltd.			
	Address: Telephone number: Fax no.:		Medjugorska 59, Zagreb		
			+385 1 2409997		
			+385 1 2404039		
	e-mail of competent person:		msds@biognost.hr		
	National contact:	-			
1.4.	Emergency telephone number				
	National Protection and Rescue Direction Medical information: Other information:		ectorate:	112	
				+385 1 2348 342	
				_	

SECTION 2 HAZARDS INFORMATION						
2.1.	Classification of the substance or mixture					
2.1.1.	Classification (REGULATION (EC) No. 1272/2008 (CLP)					
	Hazard class and category code: Hazard statements*:					
	Acute Tox. 4		H302			
2.1.2.	Additional information					
	-					
*For fu	*For full text of Hazard- and EU Hazard-statements: see Section 16					
2.2.	Label elements					
	Product identification:	HEMATOXYLIN G3				
	Identification number:	-				
	Authorization no.:	-				



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Trading name:	HEMATOXYLIN G3					
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	Hazard pictograms:	GHS07			
	Signal word:	Warning			
	Hazard statements:	H302 Harmful if swallowed.			
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.			
	Supplemetal hazard information (EU):	-			
2.3.	Other hazards				
	Endocrine Disrupting Prop	erties:			
	No known endocrine disrupting properties				
	Results of PBT and vPvB assessment : According to the results of its assessment, this substance is not a PBT or a vPvB.				

SECTION 3 CC	SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS							
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)				
107-21-1/ 203-473-3/ 603-027-00-1	01-2119456816- 28-xxxx	25 - 45 %	ethylene glycol	Acute Tox. 4, H302				

SECTIO	ECTION 4 FIRST AID MEASURES				
4.1.	Description of first aid measures				
	General notes:	-			
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.			
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.			
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.			



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Trading name:	HEMATOXYLIN G3				
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	Following ingestion:		Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.		
	Self-protection of the first a	aider:	Treat symptomatically.		
4.2.	Most important symptoms	and eff	ects, both acute and delayed		
	Following inhalation:		lation of large amounts of vapors in inadequately ventilated perimeter cause coughing, sneezing, headache and nausea.		
	Following skin contact:	_	nt irritation. After short exposure, resorption effects are not likely. Long- n exposure may cause drying, cracking and tingling sensation of skin.		
	Following eye contact:		ct eye contact may cause slight to moderate irritation, lacrimation and ning sensation. If the symptoms persist, immediately call a physician.		
	Following ingestion:	burr abdo couç	llowing may cause irritation of mucosa, tingling sensation in the mouth, ning sensation; higher levels of concentration may cause nausea, ominal pain and vomiting. In case of vomiting, aspiration causes ghing, difficult breathing. Higher levels of concentration may cause ocation.		
4.3.	Indication of any immediat	e medio	medical attention and special treatment needed		
	-				

SECTIO	CTION 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: water jet				
5.2.	Special hazards arising from the substance or mixture				
	Hazardous combustion products: No information available				
5.3.	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.				
5.4.	Additional information				
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.				

SECTIO	SECTION 6 ACCIDENTAL RELEASE MEASURES				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel	For non-emergency personnel			
	Protective equipment:	Protective equipment: Use personal protective equipment (see Section 8).			



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	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	ee Section 8).			
6.2.	Environmental precautions:				
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.				
6.3.	Methods and material for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.			
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.			
6.3.3.	Other information:	-			
6.4.	Reference to other sections				
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.				

SECTIO	CTION 7 HANDLING AN STORAGE					
7.1.	Precautions for safe handling	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:	Secure proper ventilation.				
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.				
	Other measures:	-				
7.1.2.	Advice on general occupational hygiene:					
•	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.					
7.2.	Conditions for safe storage, including any incompatibilities					



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	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

	SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION							
8.1. Control parameters								
Substance CAS No Occupational exposure limit values/short term values	Biological limit values							
ppm mg/m³	_							
Ethylene glycol 107-21-1 20/40 52/104 No	o information available							
Substance name:								
EC No: - CAS No: -								
DNEL								
Industrial								
Route of Acute Acute Chronic	Chronic							
exposure: effect local effect systemic effect local	effect systemic							
Oral	-							
Inhalation - 35 mg/ kg (ethylene glycol)								
Dermal	106 mg/kg (ethylene glycol)							
Critical physical parameters: solubility, flammability, corrosivity:								
Consumer								



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Trading name:	HEMATOXYLIN G3					
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Product	Loue.	HEIVIGS-UT-X***		Revisio	m date.	03 April 2023	version. 7	
Route of		Acute		Acut		Chronic	Chronic	
exposure	•	effect local	•	effect sys	temic	effect local	effect systemic	
Oral		-	-			-	-	
Inhalation	ı	-	-			7 mg/kg (ethylene glycol)	-	
Dermal		-	-			-	53 mg/kg (ethylene glycol)	
PNEC								
Environme	ental prote	ction target			PNEC			
Fresh wate	er				10 mg/l ((ethylene glycol)		
Freshwater sediments					37 mg/kg	g (ethylene glycol)		
Marine wa	Marine water				1 mg/l (e	thylene glycol)		
Marine se	Marine sediments				3.7 mg/k	g (ethylene glycol)		
Food chain					No infor	mation available		
Microorganisms in sewage treatment					199.5 mg/l (ethylene glycol)			
Soil (agricultural)				1.53 mg/kg (ethylene glycol)				
Air					No infor	mation available		
8.2.	Exposur	e controls						
8.2.1.	Enginee	ring measures						
	measure	meacures to prevent evangure			Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
		tructural measures to prevent xposure: Organisational measures to Organi			No information available Organization of work in order to reduce other worker's influence during work process.			
	_							
	·				re proper workspace ventilation in order to keep entration levels in air below permitted levels.			
8.2.2.	Persona	l protection equip	ment					
8.2.2.1.	Eye and	face protection:		Safety g	glasses tha	t stick to face (prevent	ing splashing) (EN 166) or	
8.2.2.2.	Skin pro	otection						
	∐and ar	rotaction	Protec	_	ves must be according to standard EN 374. material: nitrile rubber			
	nanu pr	rotection:			hickness: ≥ nrough tim	:0.11 mm ne: >480 min		



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Trading name:	HEMATOXYLIN G3					
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	Other skin protection:		Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).				
8.2.2.3.	Respiratory protection:	filter f	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point $>65^{\circ}$ C) acording to EN 14387) used when concentration levels exceed GVI.				
8.2.2.4.	Thermal hazards:	No information available					
8.2.3.	Environmental exposure controls						
	Substance/mixture related measures to prevent exposure:		See Section 6				
	Structural measures to prevent exposure:		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				

1.	Information on basic physical and che	mical properties	
		Value	Method
	Physical state:	liquid	No information available
	Color:	dark red	No information available
	Odour/odour threshold:	no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available



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Trading name:	HEMATOXYLIN G3					
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	Particle characteristics:	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.			
10.3.	Possibility of hazardous reactions:	With strong oxidants, sodium-hydroxide, sulfuric acid, aluminum.			
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.			
10.5.	Incompatible materials:	Aluminum.			
10.6.	Hazardous decomposition products:	No information available.			

Acute toxic	n on hazard classes as				
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	anhydrous (ECHA)	rabbit	LD ₅₀	_	7.712 mg/kg (ethylene glycol)
Dermal exposure:	anhydrous (ECHA)	rat	LD ₅₀	-	>3.500mg/kg (ethylene glycol)
Inhalation exposure:	No information available	_	LC ₅₀	_	_
Specific tar	get organ toxicity – si	ngle exposure	(STOT SE):		
	Specif	ic effects	Target	organ	Note
Oral exposure:	No information	available	No informatio	n available	-
Dermal exposure:	No information	available	No information available		_
Inhalation exposure: No information available		available	ble No information available -		-
Respiratory	irritation:	No info	rmation available		
		No info	rmation available		
irritation ar	nd corrosion				



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Trading name:		HEMATOXYLIN G3						
Product code:	HEMG3-OT-X	** Re	vision date:	03 April 202	Wersion:	7		
						·		
Skin irritation:	-	rabb	it -	-	Slight irritation glycol)	on (ethylene		
Eye irritation:	24 h	rabb	it -	-	Slight irritation glycol)	on (ethylene		
Sensitiza	ation							
Dermal exposure	: No information	n available						
Inhalation exposure:	No information	n available						
Sympto	ms related to the p	hysical, chemic	al and toxicolo	gical characteristi	ics			
Oral exposure:	No informat	ion available						
Dermal exposure	: No informat	ion available						
Inhalation exposi	ure: No informat	ion available						
Eye exposure:	Causes serio	ous eye damage	9					
i								
Repeate	d dose toxicity (sub	pacute, subchro	onic, chronic)	:		-		
	Dose	Exposure time	Species	Method	Evaluation	Note		
Subacute oral	No information available	No information available	No information available	No information available	No information available	-		
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-		
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	_		
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-		
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	_		
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-		
Chronic oral	No information available	No information available	No information available	No information available	No information available	-		



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Trading name:				HEM	1AT(OXYLIN G3		_		
Product code:	HE	MG3-OT-X*	* R	Revision dat	e:	03 April 2023	3	Version:	7	
Chronic dermal	dermal No information ir		No information available	formation information		No information available	No information available		-	
Chronic inhalation	No availa	information able	No information available	No information available	on	No information available	No in availa	formation ble	-	
Specific	target	organ toxicit	v – repeated	exposure (S)	OT F	RF):				
- 	<u>-</u>	1	pecific effect			Target orga	ın		Note	
Subacute oral			tion availabl		No i	nformation avail		_		
Subacute derma		No informa	ition available	e	No i	nformation avail	able	-		
Subacute inhalat	ion	No informa	ition available	e	No i	nformation avail	able	-		
Subchronic oral		No informa	ition available	e	No i	nformation avail	able	-		
Subchronic derm	nal	No informa	ition available	e	No i	lo information available		-	-	
Subchronic inhal	ation	No informa	ition available	on available No		No information available		-	-	
Chronic oral		No informa	ition availabl	on available No		No information available		-		
Chronic dermal		No informa	ition availabl	e	No i	nformation avail	able	-		
Chronic inhalation	n	No informa	ition availabl	e	No i	nformation avail	able	-		
:										
CMR eff	fects (c	arcinogenicit	y, mutagenic	ity, reproduc	tive t	oxicity)				
Carcino	genicity	y:	Current	studies on te	est ar	nimals did not in	dicate o	arcinogenio	effects.	
Mutage	<u>-</u>	n-vitro:	Current	in vitro tes	ts di	d not indicate r	nutager	nic effects.		
Genoto	xicity:			rmation avai						
Mutage	·····					d not indicate m	nutager	ic effects.		
Germ ce	ell muta	agenicity:		rmation avail						
Reprodi	uctive t	oxicity:	No tox organs.		rodu	ctive organs w	as dete	ermined in	reproductive	
Summa	ry of ev	aluation of t	he CMR prop	perties: -						
11.2. Informa	tion or	other hazar	ds:							
11.2.1. Endocri	ne disri	upting prope	rties:							
No k	nown	endocrine affect huma	disrupting							
11.2.2. Other in										
_										



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Trading name:		HEMAT	OXYLIN G3		
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

SECTION 12 EC		ICAL INFOR	RMATION	l:					
12.1. Toxicit	У		1				Ī		
Acute (short-tertoxicity	rm)	Dose	Exposu time	re Species	М	ethod	Eval	uation	Note
Fish		LC ₅₀	96 hour	rs Fish		No rmation ailable		60 mg/l ne glycol)	-
Crustacea:		EC ₅₀	48 hour	s water flea		No rmation ailable		0 mg/l ne glycol)	-
Algae/aquatic p	olants	IC ₅₀	8 days	algae		No rmation ailable		3.000 mg/l ne glycol)	_
Microorganism	S	LC ₅₀	72 hour	·s -	-			-	_
Chronic toxicity	′	Dose	Exposu time	Shacias	M	ethod	Eval	uation	Note
Fish		LC ₅₀	96 hour	No information	into	rmation lable	on No information available		-
Crustacea:		EC ₅₀	48 hour	No information available	into	rmation lable	: ayailabla		_
Algae/aquatic p	olants	IC ₅₀	72 hour	No informatio available	ınto	rmation lable	No info		_
Other organism	1S	-	-	-	-		-		_
12.2. Persist	ence a	nd degradab	oility						
Abiotic	c degra	dation							
	Deg	radation hal	f-lives	Method			Evaluati	on	Note
Marine water	No inf	ormation av	ailable	No information av	ailable	No info	mation a	vailable	-
Fresh water	No inf	ormation av	ailable	No information av	ailable	No info	mation a	vailable	-
Air	No inf	ormation av	ailable	No information av	ailable	le No information available		-	
Soil	No inf	ormation av	ailable	No information av	ailable	No info	mation a	vailable	-
1									
Biodeg	gradati	on	1		1				
% Degradation	1	Time (days	5)	Method		Evaluat	ion	N	ote
No information available		inforr iilable		No information available		o informa ailable	tion	No informa available	tion



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Trading name:						HE	MATC	XYLIN G3		·	
Produc	ct code:	НЕ	MG3-OT-	X**	Revi	ision da	ate:	03 April 202	23	Version:	7
12.3.			e potentia								
	1		cient: n-oc	tanol/wa							
Valu	e C		tration	рН	°C		thod	Evalu			Note
-	No	info ilable	ormation	-	: <u> </u>	No info availabl		n No inform available	nation	-	
	ava	парте				avallabi	е	avaliable			
	Pieconce	ntrati	on factor (I	DCE\							
\/	alue	nu all	on factor (I Specie			Method		Evaluati	on		Note
	rmation	No	•	ormation		ormatio		Evaluation No information		No information	
availabl			ilable	Offication	availab		11	available	OH	available	lation
		i			ī.			i		1	
	Chronic	ecotox	cicity								
	Value		Dos	_ E>	kposure	Cna	. si a s	Mathad	ر. در	luation	Note
	Value		Dos	е	time	Spe	ecies	Method	EVa	luation	Note
				No		No		No	No info	ormation	
Chronic	toxicity o	n fish	LC ₅₀		ormation ilable	inforn availa	nation	information available	availab		-
				ava No		No	DIE	No			
	toxicity o		EC ₅₀		ormation		nation	information		ormation	-
crustace	ea (<i>Daphn</i>	ia)		ava	ilable	availa	ble	available	availab	oie	
12.4.	Mobility	in soil									
	Known o	r pred	licted distri	bution in	environn	mental c	ompart	ments:			
	No infor	matior	n available								
	Surface t	ensior	า:								
	Value	9	°C		Concentra	ation		Method		N	ote
	No		No	N	o informa	ation	No inf	ormation			
	informat		informatio	n i	vailable	2011	availal		-		
	available		available								



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	Adsorption / desorption				
Transpo	rt A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-wat	er No information available	No information available	No information available	No information available	-
Water-a	ir No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-
12.5	Davids of DDT and DD access				
12.5.	Results of PBT and vPvB asse		contain any DPT or y	DuP substances	
	Based on available data, the	product does not o	Lontain any PBT OF V	YPVB SUDStances.	
12.6.	Endocrine disrupting propert	ies			
12.0.	No known endocrine disrupt		affect the environm	nent	
	110 known chaochine aisrapt	ing properties that	. arrect the crivilorin	iciic.	
12.7.	Other adverse effects				
12.7.	Other adverse effects No adverse effects are expec	ted.			
12.7.	Other adverse effects No adverse effects are expec	ted.			
	No adverse effects are expec				
SECTIO	No adverse effects are expec				
SECTIO	No adverse effects are expec	TIONS			
SECTION 13.1.	No adverse effects are expect N 13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposa Submit for disposal to the	TIONS	rized by the Ministr	y of Environmental	and Nature
SECTION 13.1.	No adverse effects are expected N 13 DISPOSAL CONSIDERAL Waste treatment methods Product/Packaging disposa	TIONS	rized by the Ministr	y of Environmental	and Nature
SECTION 13.1.	No adverse effects are expect N 13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposa Submit for disposal to the	TIONS al: legal person autho		y of Environmental	and Nature
SECTIOI 13.1.	No adverse effects are expected No adverse effects are expected No. 13 DISPOSAL CONSIDERAL Waste treatment methods Product/Packaging disposal Submit for disposal to the Protection.	TIONS al: legal person autho		y of Environmental	and Nature
SECTIOI 13.1.	No adverse effects are expected no adverse effects and expected no adverse effects are expecte	TIONS al: legal person autho		y of Environmental	and Nature
SECTIOI 13.1. 13.1.1.	No adverse effects are expected no adverse effects and expected no adverse effects are expecte	TIONS al: legal person authorations according to		y of Environmental	and Nature
SECTIOI 13.1.	No adverse effects are expect N 13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposal Submit for disposal to the Protection. Waste codes/waste design No information available	TIONS al: legal person authorations according to		y of Environmental	and Nature
SECTIOI 13.1. 13.1.1.	No adverse effects are expect N 13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposal Submit for disposal to the Protection. Waste codes/waste design. No information available Waste treatment – relevant	TIONS al: legal person authorations according to		y of Environmental	and Nature
SECTIOI 13.1. 13.1.1.	No adverse effects are expect N 13 DISPOSAL CONSIDERA Waste treatment methods Product/Packaging disposal Submit for disposal to the Protection. Waste codes/waste design. No information available Waste treatment – relevant	TIONS al: legal person author ations according to	·	y of Environmental	and Nature



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Trading name:	HEMATOXYLIN G3							
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13.1.5.	Other disposal recomme	endations:					
	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 pro	ovisions:					
	-						
	•						
SECTION	I 14 TRANSPORT INFORM	MATION					
	Transporting/shipment by	road (ADR)					
UN num	ber:	Not subject to transport regulations.					
UN prop	er shipping name:	-					
Transpor	t hazard class(es):	-					
Packing	group:	-					
Environn	nentally hazardous:	-					
Special p	recautions for user:	-					
	Transporting/shipment by	rail (RID)					
UN num	ber:	Not subject to transport regulations.					
UN prop	er shipping name:	-					
Transpor	t hazard class(es):	-					
Packing	group:	-					
Environn	nentally hazardous:	-					
Special p	recautions for user:	-					
	Inland waterway transport	(ADN)					
UN num	ber:	Not subject to transport regulations.					
UN prop	er shipping name:	-					
Transpor	t hazard class(es):	-					
Packing	group:	-					
Environn	nentally hazardous:	-					
Special p	recautions for user:	-					
	Transporting/shipment by	sea (IMDG)					
UN num	ber:	Not subject to transport regulations.					
UN prop	er shipping name:	-					
Transpor	t hazard class(es):	-					
Packing	group:	-					
Environn	nentally hazardous:	-					



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Trading name:		HEMATOXYLIN G3						
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Special precautions for us	er: -
Transporting/shi	oment by air (ICAO-TI/IATA-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name	: -
Transport hazard class(es)	: -
Packing group:	-
Environmentally hazardou	s: -
Special precautions for us	er: -
Further information:	The product is not subject to classification.

SECTI	ON 15 REGULATORY INFO	RMATION			
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorization and/or rest	rictions of use			
	Authorizations:	-			
	Restrictions:	-			
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);			
	Information according 19 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-			
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act			



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

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15.2.	Chemical safety assessment
	None

SECTIO	ON 16 Other information			
16.1.	Indication of changes:	-		
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative		
16.3.	Key literature references and source of data:	-		
16.4.	Classification and procedure 1272/2008 (CLP)	used to derive the classification for mixture according to Regulation (EC)		
Classifi	cation	Classification procedure		
_		-		
16.5.	Relevant H statements (numb	er and full text)		
	H: 302	Harmful if swallowed.		
16.6.	Training advice:	-		
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings o 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



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

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Trading name:	SUDAN BLACK B REAGENT				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

1.1	Product identifier					
	Trading name:	SUDAN BLA	SUDAN BLACK B REAGENT			
	Chemical name:	-				
	Catalogue number:	SBB-OT-X**				
1.2	Relevant identified use	es of the subst	tance or n	nixture and uses advised against		
	Uses:		For use	in hematology, used with Sudan Black B kit.		
	Uses advised against:		Only the	e identified uses are advised.		
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.			
1.3	Details of the supplier of the safety data sheet					
	Supplier:		BioGnost Ltd.			
	Address:	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2409997			
	Telefax.:		+385 1 2404039			
	e-mail of competent p	erson:	msds@biognost.hr			
	National contact:		-			
1.4	Emergency telephone number					
	National Protection ar	National Protection and Rescue Dire		112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	ON 2. Hazards identification					
2.1	Classification of the substance or mixture					
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)					
	Hazard class and category code:	Hazard statements*:				
	Flam. Liq. 2 H225					
	Acute Tox. 4	H302				
	Acute Tox. 4	H312				
	Acute Tox. 4	H332				
	Skin Irr. 2	H315				
	Eye Irr. 2	H319				
	Muta. 2	H341				
	STOT RE 2	H373				
2.1.2.	Additional information					
	-					



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

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Trading name:	SUDAN BLACK B REAGENT				
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Label elements	
Product identification:	SUDAN BLACK B REAGENT
Identification number:	-
Authorization number:	-
Hazard pictograms:	GHS02 GHS07 GHS08
Signal word:	Danger
Hazard statements:	 H225 Highly flammable liquid and vapor. H302+H312+H332 Harmful if swallowed, in contact with skin and if inhaled. H315 Causes skin irritation H319 Causes serious eye irritation H341 Suspected of causing genetic defects. H373 May cause damage to organs through prolonged or repeated exposure.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces Do r smoke. P280 Wear protective gloves/protective clothing/eye/protection/fac protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P311 IF exposed or concerned: Call a POISON CENTER or doctors.



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

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

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Trading name:	SUDAN BLACK B REAGENT					
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

	Supplemetal hazard information (EU):				
2.3	Other hazards				
	Endocrine Disrupting Properties:				
	No known endocrine disrupting properties				
	Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a				
	PBT or a vPvB.				

CAS/	mposition/inform			
EC/	REACH Registration	Weight % content (or	Identification name	Classification according to Regulation (EC) No 1272/2008
Index number	No	range)	Tachtinead.on Hame	(CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610- 43-xxxx	50 - 70 %	ethanol	Flam. Liq. 2; H225
108-95-2/ 203-632-7/ 604-001-00-2	01-2119471329- 32-xxxx	4 - 5 %	phenol	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Skin Corr. 1B; H314 Muta. 2; H341 STOT SE 2; H373

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



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

SECTI	ECTION 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					
	Cool endangered receptacles with contaminate the environment with	water spray. Collect contaminated fire fighting water separately. Do not a extinguishing media.				

SECTIO	CTION 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. Keep away from ignition sources.			
	Emergency procedures: Mark the area using proper signs.				
6.1.2.	For emergency responders:				
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).				
6.2	Environmental precautions:				



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Trading name:	SUDAN BLACK B REAGENT					
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

	Do not let product enter drains. Risk of explosion.					
6.3	Methods and material for cor	ntainment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Cover drains Collect hind, and himh off shills				
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.				
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).				
6.4	Reference to other sections					
	See Section 7 for information on safe handling.					
	See Section 8 for information	on personal protection equipment.				
	See Section 13 for disposal 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.				
	Measures to prevent aerosol and dust generation	າ:	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. The	roughly was	h hands after work and before eating.				
7.2	Conditions for safe storage, including any incomp	oatibilities					
	Technical measures and storage conditions:	well ventila	htly closed and upright set containers in a ated storage rooms at temperatures ranging 25 °C. Protect from heat and direct sunlight.				
	Packaging materials:	Manufactu	rer's original packaging.				
	Requirements for storage rooms and vessels:	Keep away tightly clos	from food and drink. Keep the containers sed.				



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

SECTION 8. Expos	ure contr	ols/perso	nal pr	otection					
8.1 Control pa	ntrol parameters								
Substance	CA	CAS No		Occupational exposure limit values/short term values			Biological limit values		
			р	ppm		mg/m³			
Ethanol		64	-17-5	10	00/-	1	900/-		-
Phenol	nenol 108-95-2		2	2/4		4 8/16		mg/g of creatinine (0.14 /mol of creatinine), end of t, urinary excretion	
Substance name: EC No:	-	CAS No	·:	_					
DNEL						1			
				Ind	ıstrial				
Route of	Acı	ute		Acute		Ch	ronic		Chronic
exposure:	effect	local	effe	ct systemic		effe	ct local		effect systemic
Oral	-		-		-				-
Inhalation	1900 mg (ethanol	•	-		-				380 mg/m³ (ethanol) 8 mg/m³ (phenol)
Dermal	-		-		-				343 mg/kg (ethanol) 1.23 mg/kg (phenol)
Critical physical pa	rameters:	solubility,	flamm	ability, corre	osivity:		-		
		,			sumer				
Route of	А	cute		Acute		Ch	ronic		Chronic
exposure:	effe	ct local	effe	ct systemic		effe	ct local		effect systemic
Oral	-		-		-				87 mg/kg (ethanol) 0.5 mg/kg (phenol)



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Inhalation	950 mg/ m ³ (ethanol)	-	-		114 mg/m³ (ethanol) 0.452 mg/ m³ (phenol)		
Dermal	-	-	-		206 mg/kg (ethanol) 0.5 mg/kg (phenol)		
PNEC							
Environmental p	rotection target		PNE	С			
Fresh water				0.96 mg/l (ethanol) 0.0077 mg/l (phenol)			
Freshwater sediments				3.6 mg/kg (ethanol) 0.09125 mg/kg (phenol)			
Marine water			0.79 mg/l (ethanol) 0.00077 mg/l (phenol)				
Marine sedimen	ts			2.9 mg/kg (ethanol) 0.00915 mg/kg (phenol)			
Food chain			380-	380-720 mg/kg (ethanol)			
Microorganisms	in sewage treatment		2.1 n	2.1 mg/l (phenol)			
Soil (agricultural)				0.63 mg/kg (ethanol) 0.136 mg/kg (phenol)			
Air			no ir	formation available			

8.2	Exposure controls				
8.2.1.	Appropriate engineering controls				
	Substance/mixture related measure prevent exposure during identified	nrotective equipment 1)0 not eat drink or smoke in			
	Structural measures to prevent exposure:		In accordance with Section 7.		
	Organisational measures to preven exposure:	nt	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent exp	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.	· · · · · · · · · · · · · · · · · · ·	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	protection			



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	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: 0.70 mm Break through time: > 480 min Splash contact: Gloves material: nitrile rubber Glove thickness: 0.40 mm Break through time: > 120 min			
	Other skin protection:	During everyday work use cotton clothing (EN 340) 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.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.			
8.2.2.4.	Thermal hazards:	No information available			
8.2.3.	Environmental exposure controls				
	Substance/mixture related measures to prevent exposure:	See Section 6			
	Structural measures to prevent exposure:	Use modern equipment.			
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.			
	Technical measures to prevent exposure:	See Section 6			

SECTION 9. Physical and chemical properties						
9.1	Information on basic physical and chemical properties					
		Value	Method			
	Physical state:	liquid	No information available			
	Colour:	black	No information available			
	Odour/odour threshold:	mild phenol like/no information available	No information available			
	Melting point / freezing point:	No information available	No information available			
	Boiling point or initial boiling point and boiling range:	No information available	No information available			
	Flammability:	No information available	No information available			



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	Initial boiling point and boiling range:	No information available	No information available			
	Flash point:	21°C	No information available			
	Lower and upper explosion limit:	No information available	No information available			
	Flash point:	No information available	No information available			
	Auto-ignition temperature:	No information available	No information available			
	Decomposition temperature:	No information available	No information available			
	pH:	No information available	No information available			
	Kinematic viscosity:	No information available	No information available			
	Solubility:	No information available	No information available			
	Partition coefficient n- octanol/water (log value):	No information available	No information available			
	Vapour pressure:	No information available	No information available			
	Density and/or relative density:	No information available	No information available			
	Relative vapour density:	No information available	No information available			
	Particle characteristics:	No information available	No information available			
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 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.			

SECTION 11. Toxicological information								
11.1	Information on toxicological effects							
	Acute toxicity:							
Route of exposure		Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results		
Oral:		-	rat	LD ₅₀	-	10.470 mg/kg (ethanol)		
Dermal:		-	rat	LD ₅₀	-	660 mg/kg (phenol)		
Inhalatio	n:	-	rat	LC ₅₀	4 h	124.7 mg/l (ethanol)		



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6 :6			(CTOT CE)			
Specific	target organ toxicity		sure (STOT SE):	_		
		fic effects		Target organ		Note
Oral:		o information available		rmation availab		
Dermal:		o information available		rmation availab		
Inhalation:	No information	available	No info	rmation availab	le -	
Aspirati	on hazard:	No	information av	ailable.		
Irritatio	n and corrosion					
:	Exposure tir	ne Species	Evaluation	Method		Note
Skin corrosion/irritation	on:	in vitro study	-	OECD 431	causes burns	s (phenol
Serious eye damage/irritatio	- n	rabbit	-	OECD 405	corrosive (ph	nenol)
Sensitiz	ation					
Skin sensitization	n: No info	rmation availa	ble.			
Respiratory sens	itization: No info	rmation availa	ble.			
Sympto	ms related to the phy	ysical, chemical	and toxicologi	cal characterist	ics	
Oral exposure:	No information	n available.				
Dermal exposure	e: No informatio	on available.				
Inhalation expos	ure: No informatio	on available.				
Eye exposure:	No informatio	on available.				
Repeate	ed dose toxicity (suba	cute, subchror	nic, chronic)			
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	_
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-



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

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

CMR effects (carcinogenicity; mutagenicity; reproductive 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		
Reproductive toxicity:	Based on available data, the classification criteria are not met		



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	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:			

12.1 Toxicity	y					
Acute (short- term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Leuciscus idus (Golden orfe; ethanol) Oncorhynchus mykiss (rainbow trout; phenol)	-	-	8.140 mg/l (ethanol) 5.0 mg/l (phenol)
Crustacea:	EC ₅₀	48 hours	Daphnia magna (Water flea)	-	-	7.800 mg/l (ethanol) 3.1 mg/l (phenol)
Algae/aquatic plants	IC ₅₀	7 days	green algae	-	-	5.000 mg/l (ethanol) 61.1 mg/l (phenol)
Other organisms	-	-	-	-	-	-
Chronic (long- term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	-	-	-
Crustacea:	EC ₅₀	48 hours	No information available	-	-	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	-	-	-
Other organisms	-	-	-	_	-	-

12.2 Persistence and degradability



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ADIOUG	deg	radation						-		
	D	egradation h	alf-lives		Method		Evaluation	1		Note
Marine water	No	information	available		No information available No information			-		
Fresh water	No	information a	available	No ir availa	nformation able		information lable		_	
Air	No	information	available	No ir availa	nformation able		information lable		_	
Soil	No	information	available	No ir availa	nformation able		information lable		-	
Biodeo	ırada	tion								
% Degradation	*	Time (days)		Method	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Evaluation			Note
94% (ethanol)		No ir available	nformation	OECI	O 301E		information lable	rea	readily biodegradable	
85% (phenol)		14 days		OECI	O 301C	No information available readily by		adily bio	odegradable	
		ative potentia ter partition o		log Ko	w)					
Value	Со	ncentration	рН	°C	Method		Evalua	ition		Note
-0,31 (ethanol)	_		-	-	experimental		-			ccumulation is expected
1.47 (phenol)	-		-	30 °C	ECHA		-			ccumulation is expected
Biocon	centr	ation factor ((BCF)							
Value		Speci	es		Method	Evaluation		n		Note
No information available		No in available	formation	No information available				n	-	
Chroni	c eco	toxicity								
		osure	Species		Method	Evalua	ıtian.	Note		



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Chronic to	kicity on fi	sh LC ₅₀	information ir	lo nformation vailable	No inform availab	ation i	No nformation available	-	
Chronic tox crustacea (•	EC ₅₀	No No information ir	lo nformation vailable	No inform availab	ation i	No nformation available	-	
12.4 M	obility in s	soil							
Kr	nown or pi	redicted distributi	on in environmen	tal compart	ments:				
No	o informat	ion available							
Su	ırface tens								
	Value	°C	Concentratio	n	Metho	od		Note	
	o formation ailable	No information available	No informatio available	n No inf availal	ormatio ole	n	-		
Ac	dsorption ,	/ desorption							
Transport	•	D coefficient nry's constant	log Kow	Evaporati	on rate	М	ethod	Note	
Soil-water	No availab	information le	No information available	No inform available	nation	No info	ormation le	-	
Water-air	No availab	information le	No information available	No inform available	nation	No info	ormation le	-	
Soil-air	No availab	information le	No information available	No inform available	nation	No info	ormation le	-	
		BT and vPvB asses			DD=	D. D			
Ва	ised on av	allable data, the p	product does not o	contain any	PBT or v	/PvB sub	stances.		
12.6. En	docrine d	isrupting properti	es						
Ва	sed on av	ailable data, does	not contain endo	ocrine disrup	otors.				
12.7. Ot	her adver	se effects							
		elevant information	on available.						
SECTION 1	3. Dispos	al consideration	s						



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13.1	Waste treatment methods			
13.1.1.	Product/Packaging disposa	ıl:		
	Submit for disposal to the I Protection.	egal person authorized by the Ministry of Environmental and Nature		
13.1.2.	Waste codes/waste designa	ations according to Law:		
	15 01 10*: Packaging that c substances	ontains residual hazardous substances or is contaminated with hazardous		
13.1.3.	Waste treatment – relevant	information:		
	No information available			
13.1.4.	Sewage disposal – relevant	information:		
	Waste must not be dispose	ed 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 provis	sions:		
	Disposal must be made acc	ording to official regulations.		
SECTIO	N 14 TRANSPORT INFORMA	TION		
	Transporting/shipment by ro	ad (ADR)		
UN num	ber:	1170		
UN prop	er shipping name:	Ethanol solution		
Transpo	rt hazard class(es):	3		
Packing	group:	II		
Environr	nentally hazardous:	-		
Special p	orecautions for user:	-		
	Transporting/shipment by rai	il (RID)		
UN num	ber:	1170		
UN prop	per shipping name:	Ethanol solution		
Transpo	rt hazard class(es):	3		
Packing	group:	II .		



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

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



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

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



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16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classification		า	Classification procedure	
_			-	
16.5.	Relevant H statements (num		umber and full text)	
		H225	Highly flammable liquid and vapor.	
		H301	Toxic if swallowed.	
		H302	Harmful if swallowed.	
	H:	H311	Toxic in contact with skin.	
		H312	Harmful in contact with skin.	
		H314	Causes severe skin burns and eye damage.	
		H315	Causes skin irritation.	
		H319	Causes serious eye irritation.	
		H331	Toxic if inhaled.	
		H332	Harmful if inhaled.	
		H341	Suspected of causing genetic defects.	
		H373	May cause damage to organs through prolonged or repeated exposure.	
16.6.	. Training advice: -		-	
рі			** "X" in the product code marks different volumes (different packagings of the product)	
16.7.	ins		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.	

ANN	NEX: Exposure scenario resulting to chemical safety assessment
-	