

P.A.S. DIASTASE KIT

The kit contains:

Alpha-amylase, solution
BioSchiff reagent
Bluing reagent
Hematoxylin ML
Periodic acid, 0.8% solution



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Trade name:		ALPHA-AMYLASE, SOLUTION							
Product code:	ALF-OT-X**	Date of compilation:	21 Dec 2022	Version:	2				

1.1.	Product identifier					
	Trade name:	ALP	HA-AMYLASE, SOLU	ITION		
	Chemical name:	-				
	Catalogue number:	ALF	-OT-X**			
1.2.	Relevant identified us	Relevant identified uses of the substance or mixture and uses advised against				
	Uses: For		For differentiation	between glycogen and P.A.Spositive structures		
	Uses advised against: Or		Only the identified	uses are advised.		
	Reason why uses advised re		registered at the A	he product is intended for use only as an <i>in vitro</i> diagnostic medical device, egistered at the Agency for Medicinal Products and Medical Devices and nere is no reason to use it for other purposes.		
1.3.	Details of the supplier	Details of the supplier of the safety data sheet				
	Supplier:		BioGnost Ltd.	BioGnost Ltd.		
	Address:		Medjugorska !	Medjugorska 59, Zagreb		
	Telephone number:		+385 1 240999	+385 1 2409997		
	Telefax:	Telefax:		+385 1 2404039		
	e-mail of competent	oerson	: <u>msds@biogno</u>	msds@biognost.hr		
	National contact:		-	-		
1.4.	Emergency telephone	Emergency telephone numbers				
_	National Protection a	nd Res	cue Directorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	TION 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: Warning statements*:						
	Respiratory sensitisation. Category 1 H334						
2.1.2.	Additional information						
	-						
* For fu	ıll text of Hazard- and EU Hazard	-statements: see S	ECTION 16				
2.2.	Label elements						
	Product identification: ALPHA-AMYLASE, SOLUTION						
	Identification number:	Identification number: -					
	Authorisation number:	-					



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	Hazard pictograms:	GHS08		
	Signal word:	Danger		
	Hazard statement:	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.		
	Precautionary statements:	P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P284 Wear respiratory protection. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor. P501 Dispose of contents/ container to an approved waste disposal plant.		
	Supplemetal hazard information (EU):	-		
2.3.	Other hazards			
	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.			

SECTION 3. Con	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)						
9000-90-2/ 232-565-6/ 647-015-00-4	-	3 - 5 %	a-Amylase	Resp. Sens. 1; H334						

SECTI	SECTION 4. First aid measures				
4.1.	. Description of first aid measures				
	General notes:	No acute toxicity but exposure to enzyme aerosols may cause respiratory problems and allergic reactions in sensitized persons. For longer skin contact there is the possibility of skin irritation.			
	Following inhalation:	Repeated inhalation of enzyme aerosol, which has formed through improper handling, can cause allergic reactions, including asthmatic bronchitis, in sensitive people. Provide fresh air, breath supply if necessary. If symptoms persist, consult a doctor.			



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	Following skin contact:	•	With prolonged or frequent skin contact, irritation symptoms cannot be excluded Wash off with water and soap.		
	Following eye contact: Following ingestion:		In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Remove contact lenses if necessary, protect uninjured eye.		
			Rinse mouth and drink plenty of water. Do not force vomiting. Call a docto immediately.		
	Self-protection of the first aider		-		
4.2.	Most important symptoms and effects, both acute and delayed				
	Following inhalation:		most important known symptoms and effects are described in the labelling section 2.2) and/or in section 11		
	Following skin contact:		most important known symptoms and effects are described in the labelling section 2.2) and/or in section 11		
	Following eye contact:		most important known symptoms and effects are described in the labelling section 2.2) and/or in section 11		
	Following ingestion:	The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11			
4.3.	Indication of any imme	ediate	medical attention and special treatment needed		
	-				

SECTION	SECTION 5. Firefighting measures							
5.1.	Extinguishing media							
	Suitable extinguishing media:	Co-ordinate fire-fighting measures to the surrounding fire.						
	Unsuitable extinguishing media:	-						
5.2.	Special hazards arising from the sub	ostance or mixture						
	Hazardous by products of fire:	In case of fire carbon monoxide can be released.						
5.3.	Advice for firefighters							
	Wear self-contained breathing appa	aratus for firefighting if necessary.						
5.4.	Additional information	Additional information						
	-							

SECTIO	SECTION 6. Accidental release measures				
6.1.	. Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment:	Use personal protective equipment.			
	Accident prevention methods:	Avoid aerosol formation. Provide fresh air.			



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	Emergency procedures:	Evacuate personnel to safe areas. For personal protection see section 8.		
6.1.2.	For emergency responders:			
	Self-contained open-circuit dissipation (fireproof clothi	compressed air breathing apparatus, a set for protecting the body from heat ng).		
6.2.	Environmental precautions:			
	Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.			
6.3.	Methods and materials for containment and cleaning up			
6.3.1.	Bunding, covering of drains; capping procedures:	Pick up and arrange disposal without creating dust.		
6.3.2.	Cleaning up:	Pick up mechanically or pneumatically and dispose properly. Rinse with warm water.		
6.3.3.	Other information:	-		
6.4.	Reference to other sections			
	For disposal see section 13.			

SECTIO	ON 7. Handling and storage	
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Product is not flammable. Match fire and explosion protection measures to the flammable substances in the area.
	Measures to prevent aerosol and dust generation:	Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
	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. Thore skin contact.	oughly wash hands after work and before eating. Avoid
7.2.	Conditions for safe storage, including any incompa	atibilities
	Technical measures and storage conditions:	Keep only in original packaging. Store cool, dry and odorless. Recommended storage temperature 2 -8 °C.
	Packaging materials:	Glass, high density polyethylene
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed. Store in a cool, well-ventilated area.



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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 o	n storage conditions:	-
7.3.	Specific end use(s)		
	Recommendations:	Apart from the uses m	entioned in section 1.2 no other specific uses are stipulated
	Industrial sector specific solutions:	-	

8.1. Contro	ol para	meters						
Substa	ance		CAS	No	•	l exposure limit rt term values	В	iological limit values
				ppm	mg/m³		3	
			-		-	-	No	information available
* Source - mate	erial sa	fety dat	a sheet pro	vided by	the raw mater	als supplier		
Substance:	-							
EC No:	-		CAS No:	-				
DNEL								
					Industrial			
Route of expos	ure:	Route exposu		Route	of exposure:	Route of expo	sure:	Route of exposure:
Oral		-		-		-		-
Inhalation		-		-		-		-
Dermal		-		-		-		-
Critical physica	l parar	neters: s	olubility, fla	ammabili	ty, corrosivity:	-		
					Consumer			
Route of expos	ure:	Route exposu		Route	of exposure:	Route of expo	sure:	Route of exposure:
Oral		-		-		-		-
Inhalation		-		-		-		-
Dermal		-		-		-		-
PNEC								
Environmental	protec	tion tar	get		PNEC			
Fresh water					No info	No information available		
Freshwater sed	iments	5			No info	rmation available	e	



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

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Marine wa	ater		No information available		
Marine se	diments		No information available		
Food chai	n		No information available		
Microorga	anisms in sewage treatment		No information available		
Soil (agric	ultural)		No information available		
Air			No information available		
8.2.	Exposure controls				
8.2.1.	Appropriate engineering controls	5			
	Substance/mixture related measures to prevent exposure during identified uses:	protecti	eat, drink or smoke in the workspace. Use personal ive equipment. Wash hands after handling the product and eating and/or drinking.		
Structural measures to prevent		•	te ventilation should be provided so that exposure limits exceeded. Use explosion-proof ventilation equipment.		
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.			
Technical measures to prevent exposure:		See Sec	See Section 7.2		
8.2.2.	Personal protection equipment:				
8.2.2.1.	Eye and face protection:	Safety glasses recommended. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).			
8.2.2.2.	Skin protection				
	Hand protection:	to use. glove's Dispose applical hands.	ive gloves recommended. Gloves must be inspected prior Use proper glove removal technique (without touching outer surface) to avoid skin contact with this product. e of contaminated gloves after use in accordance with ble laws and good laboratory practices. Wash and dry The selected protective gloves have to satisfy the ations of Regulation (EU) 2016/425 and the standard EN rived from it.		
	Other skin protection:	Wear la	b coat or apron.		
8.2.2.3.	Respiratory protection:	If aeros	ol formation: wear respiratory mask.		
8.2.2.4.	Thermal hazards:	No info	rmation available.		
8.2.3.	Environmental exposure controls				
	Substance/mixture related measures to prevent exposure:	See Sec	tion 6		
	Structural measures to prevent exposure:	Use mo	dern equipment.		



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anisational measures to vent exposure:	Adapt the work process to the required working conditions of the workplace.
hnical measures to prevent osure:	See Section 6

Information on basic physical an	d chemical properties	
	Value	Method
Physical state:	liquid	No information available
Colour:	brown	No information available
Odour/odour threshold:	typical/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:	5.7 – 6.7	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	Water soluble	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:	1.1 -1.2 g/ml	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
Other information		

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	No decomposition when used as intended. Risk of loss of enzyme activity at temperatures > 10°C, therefore cold storage required.
10.2.	Chemical stability:	No dangerous reactions



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10.3.	Possibility of hazardous reactions:	No information available
10.4.	Conditions to avoid:	Stable product
10.5.	Incompatible materials:	No information available
10.6.	Hazardous decomposition products:	No information available

	oxicological information								
	nation on toxicological ef	fects							
Acute	toxicity:		-						
Route of exposure:	Method	Species	LD		ve Dose or ATE _{mixture}	Expos tim	: K	esults	
Oral:	No information available	rat		informa lable	ntion	-	-		
Dermal:	No information available	rabbit		informa lable	ition	-	-		
Inhalation:	No information available	rat	1	informa lable	ntion	_	-		
Specif	ic target organ toxicity -	single expos	ure (STO	T-SE):					
	Specifi	Specific effects			Target orga		n No		
Oral:	No information av	ailable		No information available			-		
Dermal:	No information ava	ailable	No information available			lable	ole -		
Inhalation:	No information ava	ailable	No information available			lable	-		
Aspira	ition hazard:	Ins	ignificant	dange	r at normal ha	ndling te	emperature.		
Irritati	on and corrosion								
	Exposure	e time	Spe	cies	Evaluation		Method	Note	
Skin corrosion/irrita	No information	available	rabbit		Not irritating.		nformation lable	-	
Serious eye damage/irritation No information		ı available	rabbit		Not irritating.	not specified		-	
Sensit	ization								
Skin sensitization	on: No information	available							
Respiratory sensitization:	No information	available							



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Sympto	ms related to the p	hysical, chemic	cal and toxicolog	gical characterist	ics	
Oral exposure:	No informatio	n available				
Dermal exposure	e: In case of prol	onged or frequ	ent skin contact	irritation sympt	oms cannot be e	excluded
Inhalation exposure:		-		oy improper han ensitive persons		allergic
Eye exposure:	No informatio	n available				
Repeate	ed dose toxicity (su	bacute, subchro	onic, chronic)			
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-



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					1			
Subacu	te oral	No information	available	No information available	-			
Subacu	te dermal	No information	available	No information available	-			
Subacu	te inhalation	No information	available	No information available	-			
Subchr	onic oral No information a		available	No information available	-			
Subchr	onic dermal	No information	available	No information available	-			
Subchr	onic inhalation	No information	available	No information available	-			
Chronic	oral	No information	available	No information available	-			
Chronic	dermal	No information	available	No information available	-			
Chronic	Chronic inhalation No information		available	No information available	-			
	CMR effects (carcino	genicity, mutagenici	ty, reproduc	tive toxicity)				
	Carcinogenicity:		No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.					
	Mutagenicity in-vitro	:	No information available					
	Genotoxicity:		No information available					
	Mutagenicity in-vivo		No information available					
	Germ cell mutagenic	ity:	No information available					
	Reproductive toxicity	/:	No information available					
			<u>.</u>					
	Summary of evaluation properties; :	tion of the CMR	No inform	ation available				
11.2.	Information on other	hazards:						
11.2.1.	Endocrine disrupting	properties:						
	No known endo	ocrine disrupting t human health.						
11.2.2.	Other information:							
	To the best of our kr thoroughly investiga	•	cal, physical	, and toxicological properties ha	ave not been			

SECTION 12. Ecolog	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	-	-				



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			ate or t	•			V C1310	JII. Z	
Crustacea:	EC ₅₀	48 hou	ırs	No information available	No information available	-		-	
Algae/aquatic plants:	IC ₅₀	72 hou	ırs	No information available	No information available	-		-	
Other organism	S: -	-		-	-	-		-	
Chronic (long- term) toxicity	Dose		osure me	Species	Method	Evalua	tion	Note	
Fish: LC ₅₀		96 hou	ırs	No information available	No information available	No informa availabl		No information	
Crustacea: EC ₅₀		48 hou	ırs	No information available	No information available	No informa availabl		No information	
Algae/aquatic plants:	IC ₅₀	72 hou	ırs	No information available	No information available	No informa availabl		No informatio	
Other organism	s: -	-		-	-	-		_	
	;	·		1	1				
12.2. Persiste	ence and degradal	bility					:		
	ence and degradal	bility							
		•		Method	Evaluation			Note	
	degradation	alf-lives	No ir	nformation	Evaluation No information available	-		Note	
Abiotic	degradation Degradation h	alf-lives available	avail	nformation able nformation	No information			Note	
Abiotic Marine water Fresh water	Degradation h	alf-lives available available	avail No ir avail	nformation able nformation able nformation	No information available No information	-		Note	
Abiotic	Degradation No information a	alf-lives available available available	No in avail. No in avail.	nformation able nformation able nformation able	No information available No information available No information	-		Note	
Abiotic Marine water Fresh water Air Soil	Degradation No information a No information a	alf-lives available available available	No in avail. No in avail. No in avail.	nformation able nformation able nformation able	No information available No information available No information available No information	-		Note	
Abiotic Marine water Fresh water Air Soil	Degradation No information a No information a No information a No information a	alf-lives available available available	No in avail. No in avail. No in avail.	nformation able nformation able nformation able	No information available No information available No information available No information	-		Note	



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12.3.		ulative potentia vater partition o		nt (log Koy	۸/)							
Valu		oncentration		°C				Fyolyotic			Note	
No informa availabl	tion No	information iilable	pH -	-		ethod ormation le		Evaluation No information available		No info	rmation	
	Bioconcer	ntration Factor ((BCF)									
V	alue	Speci	es		Method	k		Evaluation			Note	
No info availabl	information No information		No in availa	formation ble	on		o information railable		No inforr available	nation		
	Chronic ed	cotoxicity		:		i				1		
	Value	Dos	e E	Exposure time		ecies		Method	Eν	aluation	Note	
Chronic	toxicity on	fish LC ₅₀	1	ormation ilable	No infor	mation able	i	No Information available		rmation ilable	Not expected.	
	toxicity on ea (Daphnia	: F (F0		ormation ilable	No infor availa	mation able	i	No Information available		rmation ilable	Not expected.	
12.4.	Mobility in	n soil										
	-	predicted distr	ibution i	n environi	mental o	compartr	mer	nts:				
	Surface te	nsion:										
	Value	°C		Concenti	ration		M	1ethod		Note		
	No informatio available	No information available	าท	No inform available		No info	orm		-			
	Adsorptio	n / desorption										



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Transpo	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note		
Soil-Wa	ter No information available	No information available	No information available	No information available	-		
Water-A	Water-Air No information available 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.	Results of PBT and vPvB assessm	nent					
	This substance/mixture contains toxic (PBT), or very persistent an	•	•		mulative and		
12.6.	Endocrine disrupting properties						
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.						
	according to REACH Article 57(f)	or Commission Delega		•			
12.7.	according to REACH Article 57(f)	or Commission Delega		•			
12.7.	according to REACH Article 57(f) Regulation (EU) 2018/605 at leve	or Commission Delega		•			
	according to REACH Article 57(f), Regulation (EU) 2018/605 at level Other adverse effects No information available	or Commission Delega		•			
	according to REACH Article 57(f) Regulation (EU) 2018/605 at leve Other adverse effects	or Commission Delega		•			
SECTIO	according to REACH Article 57(f) Regulation (EU) 2018/605 at leve Other adverse effects No information available N 13. Disposal considerations	or Commission Delega		•			
SECTIO	according to REACH Article 57(f) Regulation (EU) 2018/605 at leve Other adverse effects No information available N 13. Disposal considerations	or Commission Delega		•			
SECTIO 13.1.	according to REACH Article 57(f), Regulation (EU) 2018/605 at level Other adverse effects No information available N 13. Disposal considerations Waste treatment methods	or Commission Delegatels of 0.1% or higher. Description of the second o	ted regulation (EU) 2	2017/2100 or Co	mmission S/EC as well as		
SECTIO 13.1. 13.1.1.	according to REACH Article 57(f) Regulation (EU) 2018/605 at level Other adverse effects No information available N 13. Disposal considerations Waste treatment methods Product/Packaging disposal: Waste material must be disposated the product and local regulations. Handle uncleaned containers in	or Commission Delegatels of 0.1% or higher. Descriptions of the second	ted regulation (EU) 2	2017/2100 or Co	mmission S/EC as well as		
SECTIO 13.1.	according to REACH Article 57(f) Regulation (EU) 2018/605 at level Other adverse effects No information available N 13. Disposal considerations Waste treatment methods Product/Packaging disposal: Waste material must be disposated the product of	or Commission Delegatels of 0.1% or higher. Descriptions of the second	ted regulation (EU) 2	2017/2100 or Co	mmission S/EC as well as		
SECTIO 13.1. 13.1.1.	according to REACH Article 57(f) Regulation (EU) 2018/605 at level Other adverse effects No information available N 13. Disposal considerations Waste treatment methods Product/Packaging disposal: Waste material must be disposated the product of	or Commission Delegatels of 0.1% or higher. Descriptions of the second	ted regulation (EU) 2	2017/2100 or Co	mmission S/EC as well as		
SECTIO 13.1. 13.1.1.	according to REACH Article 57(f) Regulation (EU) 2018/605 at level Other adverse effects No information available N 13. Disposal considerations Waste treatment methods Product/Packaging disposal: Waste material must be disposated the product of	or Commission Delegatels of 0.1% or higher. Deserved of in accordance varions. Leave chemicals ike the product itself The product itself in according to Law:	ted regulation (EU) 2	2017/2100 or Co	mmission		



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13.1.4.	Sewage disposal – relevant information:					
	Waste must not be disposed o	f into the sewage system.				
13.1.5.	Other disposal recommendation	ons:				
	-					
13.1.6.	Relevant Community provision	ns:				
	-					
SECTION	14. Transport information					
٦	Fransporting/shipment by road	(ADR)				
UN numb	er:	Not subject to transport regulations.				
UN prope	er shipping name:	-				
Transport	hazard class(es):	-				
Packing g	roup:	-				
Environm	ental hazards:	-				
Special pr	recautions for user:	-				
٦	Transporting/shipment by rail (R	ID)				
UN numb	er:	Not subject to transport regulations.				
UN prope	er shipping name:	-				
Transport	hazard class(es):	-				
Packing g	roup:	-				
Environm	ental hazards:	-				
Special pr	recautions for user:	-				
٦	Fransporting/shipment by inland	d waterways (ADN)				
UN numb	er:	Not subject to transport regulations.				
UN prope	er shipping name:	-				
Transport hazard class(es):		-				
	Packing group: -					
Environm	rironmental hazards: -					
	pecial precautions for user: -					
]	Transporting/shipment by sea (IMDG)					
UN numb		Not subject to transport regulations.				
	er shipping name:	-				
Transport	hazard class(es):	-				



Trade name:

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	1					
Product code:	ALF-OT-X**	Date of compilation:	21 Dec 2022	Version:	2	
Packing group:		-				
Environmental haz	ards:	-				
Special precaution	s for user:	-				
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:		-				
Transport	ing/shipment by air (IC	CAO-TI/IATA-DGR)				
UN number:		Not subject to transpo	rt regulations.			
UN proper shipping name:		-				

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

Further information:

 Safety, health and environ 	Safety, health and environmental regulations/legislation specific for the substance or mixture					
EU regulations						
Authorisations and/or res	strictions 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);					



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	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act	
15.2.	Chemical safety assessment		
	None		

SECTIO	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 (num	ber and full text)		
	H: 334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.		
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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SECTI	ON 1: Identification of t	the substance	e/mixture	e and of the company/undertaking	
1.1	Product identifier				
	Trading name:	BIOSCHIFF	BIOSCHIFF REAGENT		
	Chemical name:	-			
	Catalogue number:	BS-OT-X**			
1.2	Relevant identified us	es of the sub	stance or i	mixture and uses advised against	
	Uses:		For dete	ecting aldehydes and mucous substances.	
	Uses advised against:		Only the	e identified uses are advised.	
	Reason why uses adv	ised against:	The product is intended for use only as an <i>in vitro</i> diagnostic device, registered at the Agency for Medicinal Products and Devices and there is no reason to use it for other purposes.		
1.3	Details of the supplie	Details of the supplier of the safety data sheet			
	Supplier:		BioGnost Ltd.		
	Address:		Medjugorska 59, Zagreb		
	Telephone number:		+385 1 2	385 1 2409997	
	Telefax.:		+385 1 2	2404039	
	e-mail of competent	person:	msds@b	<u>piognost.hr</u>	
	National contact:		-		
1.4	Emergency telephone	Emergency telephone number			
	National Protection and Rescue Directorate:			112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards identification					
2.1	Classification of the substance	or mixture				
2.1.1	Classification according to Reg	Julation (EC) No 1	272/2008 (CLP)			
	Hazard class and catego	ory code:		Hazard statements*:		
	-		EUH031			
2.1.2.	Additional information					
	-					
*For full	text of Hazard- and EU Hazard-	statements: see S	ECTION 16			
2.2	Label elements					
	Product identification: BIOSCHIFF REAGENT					
	Identification number:	Identification number: -				
	Authorization number:	-				



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	Hazard pictograms:	-
	Signal word:	-
	Hazard statements:	EUH031 Contact with acids liberates toxic gas.
	Precautionary statements:	P281 Use personal protective equipment as required.
	Supplemetal hazard information (EU):	-
2.3	Other hazards	
	Endocrine Disrupting Prop	erties:
	No known endocrine disrupt	ing properties
	Results of PBT and vPvB as PBT or a vPvB.	sessment: According to the results of its assessment, this substance is not a

SECTION 3. Co	mposition/information	n on ingredients		
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
7681-57-4/ 231-673-0/ 016-063-00-2	01-2119531326-45- XXXX	1 – 3 %	sodium metabisulfite	Acute Tox. 4; H302 Eye Dam. 1; H318 EUH031
7647-01-0/ 231-595-7/ 017-002-01-X	01-2119484862-27- XXXX	0.7 – 1 %	hydrochloric acid, 36.5%	Skin Corr. 1B; H314 Acute Tox. 3; H331
569-61-9/ 209-321-2/ 611-031-00-X	-	< 0.1 %	4,4'-(4-iminocyclohexa-2,5-dienylidenemethylene) dianiline hydrochloride; C.I. Basic Red 9	Carc. 1B; H350

SECTIO	SECTION 4. First aid measures				
4.1	Description of first aid measures				
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.			
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.			
	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.			



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	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.	
	Self-protection of the first aider:	-	
4.2	Most important symptoms and effe	ects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.	
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.	
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.	
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.	
4.3	Indication of any immediate medical attention and special treatment needed		
	-		

SECTIO	SECTION 5. Firefighting measures				
5.1	Extinguishing media				
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam			
	Unsuitable extinguishing media:	Water jet			
5.2	Special hazards arising from the sub	stance or mixture			
	Hazardous combustion products:	Hazardous combustion products: Sulfur oxides.			
5.3	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.				
5.4	Additional information				
	Do not contaminate the environmer	nt with extinguishing media.			

SECTIO	N 6. Accidental release measures			
6.1	Personal precautions, protective	e equipment and emergency procedures		
6.1.1.	For non-emergency personnel	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			
	Emergency procedures:	Mark the area using proper signs.		



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6.1.2.	For emergency responders	For emergency responders:			
	Use protective equipment; (see Section 8).	in case of inadequate ventilation use adequate airways protective equipment			
6.2	Environmental precautions				
	Do not dispose of in sewage Protection and Rescue Dire	ge, drainage system and waterways. In case of large spillage contact National ectorate (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 absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.			
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).			
6.4	Reference to other sections				
	See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal information.				

SECTIO	ON 7. Handling and storage				
7.1	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:		Use in well ventilated storage rooms.		
	Measures to prevent aerosol and dust generation	n:	Secure proper ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:		-		
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. Th	oroughly wa	sh hands after work and before eating.		
7.2	Conditions for safe storage, including any 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.			
	Packaging materials:	Manufactu containers	ırer's original packaging. Avoid metal		



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	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:	-

8.1 Control	parameters	;					
Substance		CA	CAS No		Occupational exposure limit values/short term values		gical limit values
				ppm	mg/m³		
sodium metabisulfite		7681-57	7-4	-/-	5/-	No inf	ormation available
Substance name:	-						
EC No:	_	CAS No	:				
DNEL							
				Industria			
Route of	Acı	Acute Acute Chronic		Chronic			
exposure:	effect	local	effect s	systemic	effect local	effect local	
Oral	-		-		-	-	
Inhalation	-		-		-	-	
Dermal	-		-		-	-	
Critical physical p	arameters: :	solubility,	flammabili	ty, corrosivity	: -		
				Consume	r		
Route of	Acı	ute	Ad	cute	Chronic		Chronic
exposure:	effect	local	effect s	systemic	effect local		effect systemic
Oral	-		-		-	_	
Inhalation	-		-		-	_	
Dermal	_		_		_	_	·



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Environm	ental protection target		PNEC		
Fresh wat	er		No information available		
Freshwate	er sediments		No information available		
Marine w	ater		No information available		
Marine se	ediments		No information available		
Food cha	in		No information available		
Microorg	anisms in sewage treatment		No information available		
Soil (agric	cultural)		No information available		
Air			No information available		
8.2	Exposure controls				
8.2.1.	Appropriate engineering contr	ols			
	Substance/mixture related measures to prevent exposure during identified uses: Structural measures to prevent exposure:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.		
			In accordance with Section 7.		
	Organisational measures to pre exposure:	event	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.		
8.2.2.	Personal protection equipment	t			
8.2.2.1.	Eye and face protection:	levels o	glasses that stick to face (EN 166) or visor in case of lower of concentration in air; protective gas mask that covers the face in case of higher levels of concentration in air.		
8.2.2.2.	Skin protection	i			
	Hand protection:	Protec	tive nitrile gloves, 0.11 mm thick (EN 374).		
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) ong sleeves (EN 340) and shoes that cover the entire foot.		
8.2.2.3.	Respiratory protection:	combi	le mask (EN 136) or half mask (EN 140) equipped with a ned "A1 + Form" filter (EN 143) used when concentration exceed GVI.		
8.2.2.4.	Thermal hazards:	No info	ormation available		
8.2.3.	Environmental exposure contro	ols			
	Substance/mixture related measures to prevent exposure:	See Se	ction 6		



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

1	Information on basic physical and	chemical properties	
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour/odour threshold:	sharp/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:	<2	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient noctanol/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		

9	SECTION	N 10. Stability and reactivity	
-	10.1	Reactivity:	No information available



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10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3	Possibility of hazardous reactions:	No information available
10.4	Conditions to avoid:	No information available
10.5	Incompatible materials:	Strong oxidants (acids).
10.6	Hazardous decomposition products:	Sulfur dioxide, sodium oxide.

11.1 Inf	ormation on toxi	cological effects				
Ac	ute toxicity:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Expo	osure time	Results
Oral:	OECD Test Guideline 401	rat (sodium metabisulphite) mouse (C.I. Basic Red 9)	LD ₅₀	-		1.540 mg/kg (sodium metabisulphite) 5.000 mg/kg (C.I. Basic Red 9)
Dermal:	OECD Test Guideline 402	rat	No information available	-		>2.000 mg/kg (sodium metabisulphite)
Inhalation:	OECD Test Guideline 403	rat	No information available	4h		>5.5 mg/l (sodium metabisulphite)
C	:C: - tt	a kandalka a shalla a sa	(CTOT CE)			
Sp	3 3	n toxicity – single exp		'araat araan		Note
Oral:	No information	pecific effects		arget organ		Note
Dermal:	No information			nation availa		
Inhalation:	No information			nation availa		
irinalation.	No imormation	i avaliable	INO IIIIOIII	iation availa	ıble -	
As	piration hazard:	No	o information avail	able.		
Irri	tation and corros	sion				
	E	xposure time	Species	Evaluati on	Method	Note
Skin corrosion/irr	itation:	-		-	-	-
Serious eye damage/irrit	ation -	-		-	-	-



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Sensiti	zation						
Skin sensitization: No information available							
Respiratory sens	itization:	No inf	ormation avail	able			
Sympto	oms relate	d to the p	hysical, chemic	cal and toxicolo	gical characteris	tics	
Oral exposure:					npanied by abdo ng and diarrhea.	ominal pains and cra	mps; higher
Dermal exposure	e: Ma	y cause sl	kin irritation.				
Inhalation expos	ure: exp	osure and		y sensitive pers	_	oncentration, prolong sm may occur, as we	-
Eye exposure:	Ма	y cause e	ye irritation.				
Repeat	ed dose to	oxicity (su	bacute, subchr	onic, chronic)			
	Do	se	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No info		No information available	No information available	No information available	No information available	-
Subacute dermal	No info		No information available	No information available	No information available	No information available	-
Subacute inhalation	No info	ormation	No information available	No information available	No information available	No information available	-
Subchronic oral	No info		No information available	No information available	No information available	No information available	-
Subchronic dermal	No info		No information available	No information available	No information available	No information available	-
Subchronic inhalation	No info		No information available	No information available	No information available	No information available	-
Chronic oral	No info		No information available	No information available	No information available	No information available	-
Chronic dermal	No info		No information available	No information available	No information available	No information available	-



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Chronic inhalation	No availa	information able	No information available	No information available	No information available	No information available	-	
Sp	ecific targe	t organ toxici	ty – repeated e	exposure (STOT	· RE):			
<u> </u>			Specific effe		Target	organ	Note	
Subacute or	al	No informa	tion available		No informa available			
Subacute de	ermal	No informa	tion available		No informa available	tion -		
Subacute in	halation	No informa	tion available		No informa available	tion -		
Subchronic	oral	No informa	tion available		No informa available	tion -		
Subchronic	dermal	No informa	tion available		No informa available	tion -		
Subchronic	inhalation	No informa	tion available		No informa available	tion -		
Chronic ora	I	No informa	tion available		No informa available	tion -		
Chronic der	mal	No informa	tion available		No informa available	tion -		
Chronic inha	alation	No informa	tion available		No informa available	tion -		
CN	AP offocts (carcinogonici	tv: mutagonicit	:y; reproductive	a toxicity)			
	rcinogenici		ty, matagemen		ation available			
	utagenicity				No information available			
	enotoxicity:				No information available			
	utagenicity	in vivo:			No information available			
	erm cell mu				No information available			
Reproductive toxicity:				ation available				
	ımmary of operties:	f evaluation	of the CN	No inform	ation available			
11.2 In	formation o	n other hazar	ds:					
11.2.1. En	docrine dis	rupting prope	erties:					



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	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
	-

SECTION 12. Ecological information								
12.1 Toxicity	12.1 Toxicity							
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		
Fish	LC ₅₀	96 hours	Golden orfe (sodium metabisulphite) Mosquito fish (hydrochloric acid)	No information available	316 mg/l (sodium metabisulphite) 282 mg/l (hydrochloric acid)	-		
Crustacea:	EC ₅₀	48 hours	Daphnia magna (sodium metabisulphite)	No information available	89 mg/l (sodium metabisulphite)	-		
Algae/aquatic plants	IC ₅₀	4 days	Green algae (sodium metabisulphite)	No information available	43.8 mg/l (sodium metabisulphite)	-		
Other organisms	-	_	-	-	-	_		
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note		
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-		
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-		
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-		
Other organisms	-	-	-	-	-	-		



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Trading nam	ie:				BIOSCHIFF I	REAGENT				
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Fresh water	No	information	available	No in	formation able	No information		-		
Air	No	information	available	No in availa	formation Ible	No information	on -	-		
Soil	No	information	available	No in availa	formation ible	No information	on -	-		
Bioc	degrada	ation								
% Degrada			(days)		Method	Evaluation	n		Note	
No information available			information	n No ir availa	formation	No information	on N	No info	ormation	
		lative poter								
Octa		ater partitio	n coefficien	t (log Ko	ow)					
Value		entratio n	рН		Method	Evaluation			Note	
-	-	-		_	_	_		-		
Bioc	concent	ration facto	r (BCF)							
Value		Spe	cies		Method	Evaluatio	n		Note	
•				formation ble	No information available		-			
Chro	onic eco	otoxicity								
Value		Dose		oosure time	Species	Method	Evalua	ation	Note	
Chronic toxicity On fish Chronic toxicity LC ₅₀ No information available		No information available	No inform on availal		-					



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Chronic t on crusta (Daphnia	icea	EC ₅₀	No informatio n available	No info	ormation ble	No infor avail	rmation able	No informati on available	-	
12.4	Mobility in	n soil								
	Known or	predicted distribut	ion in environ	mental	compartm	nents:				
	No inform	ation available								
	Surface te	nsion:								
	Value	°C	Concentr	ation	,	Metho	od		Note	
	No informatio available	No information available	No informavailable	ation	No infor available		n	-		
	Adsorptio	n / desorption								
Transpor	t i	/D coefficient enry's constant	log Kow	E۱	/aporation	rate	М	ethod	Note	
Soil-wate	er No availa	information ble	No informat available		o informat ⁄ailable	ion	No info availabl	rmation e	-	
Water-ai	r No availa	information ble	No informat available		o informat ⁄ailable	ion	No info availabl	rmation e	-	
Soil-air	No availa	information ble	No informat available		o informat vailable	ion	No info availabl	rmation e	-	
12.5.		PBT and vPvB asse								
	Substance	e(s) in the mixture o	do(es) not mee	et the cr	iteria for F	PBT or	vPvB			
12.6.	Endocrine	disrupting proper	ties							
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.									
12.7.	Other adv	erse effects								
	No inform	ation available								
SECTION	l 13. Dispo	sal consideration	S							



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Trading name:	BIOSCHIFF REAGENT				
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13.1	Waste treatment methods		
13.1.1.	Product/Packaging disposal:		
	Submit for disposal to the legal Protection.	person authorized by the Ministry of Environmental and Nature	
13.1.2.	Waste codes/waste designation	ns according to Law:	
	Packaging that contains residua	al hazardous substances or is contaminated with hazardous substances	
13.1.3.	Waste treatment – relevant info	ormation:	
	No information available		
13.1.4.	Sewage disposal – relevant info	rmation:	
	Waste must not be disposed of	into the sewage system.	
13.1.5.	Other disposal recommendation	ns:	
	authorized by the ministry in ch	s remains into the sewage system. Submit the remains to the collectors narge. Do not dispose of the packaging into the sewage system. Submit authorized by the ministry in charge.	
13.1.6.	Relevant Community provisions	5:	
	-		
SECTIO	N 14. Transport information		
	Transporting/shipment by road	(ADR)	
UN num	ber:	Not subject to transport regulations	
UN prop	er shipping name:	-	
Transpo	rt hazard class(es):	-	
Packing	group:	-	
Environr	nentally hazardous:	-	
Special p	orecautions for user:	-	
	Transporting/shipment by rail (RID)		
		Not subject to transport regulations	
UN proper shipping name:		-	
Transpo	rt hazard class(es):	-	
Packing	group:	-	
Environr	nentally hazardous:	_	



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Special precautions for user:	-
Inland waterway transport (ADN	N)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
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 (I	CAO-TI/IATA-DGR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information: -	

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



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	None	
15.2	Chemical safety assessme	ent
	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)	999/13/EC about limitation of emissions of volatile organic compounds (VOC-
	Other EU regulations:	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);

SECTIO	ECTION 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)				
Classific	cation	1	Classification procedure			
_			-			
16.5.	Rel	evant H statements (num	nber and full text)			
		302	Harmful if swallowed.			
		314	Causes severe skin burns and eye damage			
	Н	318	Causes serious eye damage.			
	•	331	Toxic if inhaled.			
		350	May cause cancer.			
		EUH031	Contact with acids liberates toxic gas.			
16.6.	Training advice:		-			
			** "X" in the product code marks different volumes (different packagings of the product)			
16.7. Further information:		ther information:	We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to chemical safety assessment
-



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

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Trading name:	BLUING REAGENT			
Product code:	BR-OT-X**	Date of compilation: 23 January 2023	Version: 7	

SECTI	ON 1: Identification of	the substanc	e/mixture a	and of the company/undertaking	
1.1.	Product identifier				
	Trading name:	BLUING RE	BLUING REAGENT		
	Chemical name:	-			
	Catalogue number:	BR-OT-X**	BR-OT-X**		
1.2.	Relevant identified us	es of the subs	stance or mi	xture and uses advised against	
	Uses:		For conve	ersion of red hematoxylin stained nuclei to blue.	
	Uses advised against:		Only the i	dentified 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:	В	BioGnost Ltd.		
	Address:	N	Medjugorska 59, Zagreb		
	Telephone number: +		-385 1 2409997		
	Fax no.: +		+385 1 2404039		
	e-mail of competent person: <u>m</u>		msds@biognost.hr		
	National contact: -				
1.4.	Emergency telephone number				
	National Protection and Rescue Dire		octorato:	112	
	National Protection ar	nd Rescue Dir	ectorate.	1.2	
	National Protection ar Medical information:	nd Rescue Dir	ectorate.	+385 1 2348 342	

SECTIO	SECTION 2. Hazards identification				
2.1.	Classification of the substance or mixture				
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)				
	Hazard class and category	y code:	Hazard statements*:		
	Not identified as hazardous subs	tance.	-		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazard-st	atements: see S	ection 16		
2.2.	Label elements				
	Product identification:	BLUING REAC	GENT		
	Identification number:	-			
	Authorization no.:	-			
	Hazard pictograms:	-			



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Trading name:		BLUING	REAGENT	
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7
Signal wo	rd.			

	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	Endocrine Disrupting Properties:	
	No known endocrine disrupting prop	erties.

SECTION 3. Composition/information on ingredients							
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)			
-	-	-	Contains no hazardous substances	-			

SECTION 4. First aid measures					
4.1.	Description of first aid measures				
	General notes:		-		
	Following inhalation: Following skin contact: Following eye contact: Following ingestion: Self-protection of the first aider:		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.		
			Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.		
			Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.		
			Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.		
			Treat symptomatically.		
4.2.	Most important symptoms and effects, both acute and delayed				
	Following inhalation: No		information available		
	Following eye contact: No i		nformation available		
			nformation available		
			nformation available		
4.3.	Indication of any immediate medical attention and special treatment needed				



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SECTI	ECTION 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	ON 6. Accidental release meas	ures				
6.1.	Personal precautions, protective equipment and emergency procedures					
6.1.1.	For non-emergency personnel					
	Protective equipment:	Use personal protective equipment (see Section 8).				
	Accident prevention methods	Evacuate members of all non-essential personnel and those members without protective equipment. 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:	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 parriers				



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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.			
6.3.3.	Other information:	-			
6.4.	Reference to other 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	ON 7. Handling and storage						
7.1.	Precautions for safe handling						
7.1.1.	Protection measures						
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do smoke.					
	Measures to prevent aerosol and dust generati	on: S	ecure proper ventilation.				
	Measures to protect the environment:		revent spilling into the sewage system and atterways.				
	Other measures:	-					
7.1.2.	Advice on general occupational hygiene:						
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.						
7.2.	Conditions for safe storage, including any incompatibilities						
	Technical measures and storage conditions:	ventila	n tightly closed and upright set containers in a well ted storage rooms, and away from sources of heat, nt, and other incompatible substances.				
	Packaging materials:	Manuf	acturer's original packaging.				
	Requirements for storage rooms and vessels:	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:		t place the unused material in the storage room onot use empty containers for storing other cals. Do not store with incompatible materials (see n 9).				
7.3.	Specific end use(s)						



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Pocomm	andations:		_					
Recommendations: Industrial sector specific solutions:		ıtions:	_					

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			
-			-	1		No information available			
Substance - name:									
EC No: -		CAS No:	-						
DNEL									
				Inc	dustrial				
Route of exposure:		Acute		Acut			roni		
Noute of exposure.	effe	ect local	effe	ect sys	temic	effe	ct lo	ocal effect systemic	
Oral	-		-			-		-	
Inhalation	Inhalation -		-			-		-	
Dermal	-		-			_		-	
Critical physical parar	neters: s	solubility, fla	mmabilit	ty, cor	rosivity:	-			
	T		T	Co	nsumer				
Route of exposure:		Acute ect local	effe	Acutect sys		Ch effe	roni ct lo		
Oral	-		-			-		-	
Inhalation	-		-			-		-	
Dermal	-		-			-		-	
PNEC									
Environmental protec	tion tar	get			PNEC				
Fresh water				No information available					
Freshwater sediments				No information available					
Marine water				No information available					
Marine sediments				No information available					
Food chain					No information available				
Microorganisms in se	wage tr	eatment			No information available				
Soil (agricultural)				No information available					



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Air			No information available			
8.2.	Francisco controlo					
	Exposure controls					
8.2.1.	Appropriate engineering		5			
	Substance/mixture relate measures to prevent exp during identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to prescribe exposure:	revent	No information available			
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equi	pment				
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166 visor.				
8.2.2.2.	Skin protection					
			ective gloves must be according to the EU Directive 2016/425/EEC and dard EN 374.			
	Hand protection:		Glove material: nitrile rubber			
			Glove thickness: ≥0.50 mm			
			Break through time: >480 min			
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) with long es (EN 13034), and shoes that cover the entire foot (EN 10335).			
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 in	formation available			
8.2.3.	Environmental exposure	controls				
	Substance/mixture related measures to prevent exposure:		See Section 6			
	Structural measures to prescribe exposure:	revent	Use modern equipment.			
	Organisational measures to prevent exposure:		Adapt the work process to the required working conditions of the workplace.			
	Technical measures to prexposure:	event	See Section 6			

SECTION 9. Physical and chemical properties



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Trading name:	BLUING REAGENT						
Product code:	BR-OT-X**	Date of compilation: 23 January 2023	Version: 7				

	Value	Method
Physical state:	liquid	No information available
Color:	ight blue	No information available
Odour/odour threshold:	no information available/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:	>8.0	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available

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

SECTION 11. Toxicological information



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Trading name:		BLUING	BLUING REAGENT					
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7				

Acute toxi	city:						
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposur	e time	Results	
Oral exposure:	No information available	-	LD ₅₀	-		-	
Dermal exposure:	No information available	-	LD ₅₀	-		-	
Inhalation exposure:	No information available	-	LC ₅₀	-		-	
Specific ta	rget organ toxicity – si	ngle exposure (STOT SE):				
•	3 3	ic effects		t organ		Note	
Oral exposure:	No information		No informati		-		
Dermal exposure:	No information	available	No information available -				
Inhalation exposure	: No information	available	No informati	on available	-		
Aspiration	hazard:	No infor	mation available				
;		:					
Irritation a	nd corrosion:						
	Exposure time	Species	Evaluation	Method		Note	
Skin irritation:	-	-	-	-	-		
Eye irritation:	-	-	-	-	_		
Sensitizatio	on						
Dermal exposure:	No information avail	able					
Inhalation exposure:	No information avail	able					
Symptoms	related to the physica	l, chemical and	toxicological chara	acteristics			
Oral exposure:	sensation; higher	levels of concen	f mucosa, tingling tration may cause uses coughing, diff	nausea, abd	ominal pa	ain and vomiting	
, , , , , , , , , , , , , , , , , , ,	concentration ma	•	ion.				



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Trading name:	BLUING REAGENT						
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7			

Inhalation exposi	ure:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.									
Eye exposure: Direct eye of sensation.			contact may cause slight to moderate irritation, lacrimation and burning								
Reneate	nd dos	e toxicity (sub	acute, subchro	onic chroni	(c)						
Repeate		Dose	Exposure time	Species	<u>C)</u>	Method	Evaluation	Note			
Subacute oral	ubacute oral No information available		No information available	No informati available	on	No information available	No informatio available	on -			
Subacute dermal	No avail	information able	No information available	ion information inf		No information available	No informatio available	n -			
Subacute inhalation	No avail	information able	No No information available available		on	No information available	No informatio available	n -			
Subchronic oral	available		No information available	No informati available	on	No information available	No informatio available	n -			
Subchronic dermal			No information available	No information available		No information available	No informatio available	n -			
Subchronic inhalation			No information available	No information available		No information available	No informatio available	n -			
Chronic oral	nronic oral No information available		No information available	No n informatio available		No information available	No informatio available	on -			
Chronic dermal	nronic dermal No information available		No information available	No informati available	on	No information available	No informatio available	on -			
Chronic No information inhalation available		No information available	No informati available	on	No information available	No informatio available	on -				
Coocitic	taract	organ tovisit	v ropested s	vnocuro (C	ת דרת						
Specific	target	1	y – repeated e pecific effects	xposure (S	IUIK	Target orga	an	Note			
Subacute oral			tion available		No ii	nformation avai		- Note			
Subacute dermal			tion available			nformation avai		-			
Subacute inhalat			tion available			nformation avai		_			



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Trading name:			BLUING REAGENT						
Produ	ct code:	BR-OT-X**	Date of compilat	Date of compilation: 23 January 2023					
Subchronic oral No informa		No informati	ion available	No ir	nformation available	-			
Subchronic dermal No information		ion available	No ir	nformation available	-				
Subchronic inhalation No information		ion available	No ir	nformation available	-				
Chronic oral No information		ion available	No ir	nformation available	-				
Chronic dermal No information		ion available	No ir	nformation available	-				
Chroni	c inhalation	No informati	ion available	No ir	nformation available	-			
	CMR effect	s (carcinogenicity;	mutagenicity; reproduc	tive to	oxicity)				
	Carcinoger	nicity:	Current studies on to	est an	imals did not indicate ca	rcinogenic effe	cts.		
	Mutagenic	ity <i>in-vitro</i> :	Current in vitro tes	sts did	d not indicate mutageni	c effects.			
	Genotoxici	ty:	No information avail	No information available					
	Mutagenic	ity <i>in-vivo</i> :	Current in vivo tes	ts dic	not indicate mutagenio	effects.			
	Germ cell r	nutagenicity:	No information available						
	Reproducti	ve toxicity:	No toxicity on reproductive organs was determined in reproductive organs.						

11.2.	Information on other hazards:							
11.2.1.	Endocrine disrupting properties:							
	No known endocrine disrupting properties that affect human health.							
11.2.2.	Other information:							
	-							

Summary of evaluation of the CMR properties:

SECTION 12. Ecologi	cal informa	tion									
12.1. Toxicity											
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note					
Fish	LC ₅₀	96 hours	No information available	No information available	-	-					
Crustacea:	EC ₅₀	48 hours	No information available	No information available	_	-					
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	_	_					
Microorganisms	LC ₅₀	72 hours	-	-	-	-					
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note					



Value

Species

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

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Trading	name	•				BLUING	S RE	AGENT			
Product code:			R-OT-X** Date of compilation: 23 January 2023							Version: 7	
Fish			LC ₅₀	96 hou	rs			information iilable	No information available		
Crustacea:			EC ₅₀	48 hou	rs	No information available		information iilable	No informat available		
Algae/aquatic plants		olants	IC ₅₀	72 hou	rs	No information available		information iilable	No informat available		
Other or	ganism	ıs	_	-		_	-		-	-	
12.2.			nd degrada	bility							
	Abiotio		adation								Note
		radation ha	lf-lives		Method		Evalua		aluation		
Marine No infe		ormation av	ailable	No	No information available		No information available		ble	-	
Fresh wa	ater	No information available No information available No inform		No informa	tion availa	ble	-				
Air		No inf	ormation av	ailable	No	information availa	able	No informa	tion availa	ble	-
Soil		No inf	ormation av	ailable	No	information availa	able	No informa	tion availa	ble	-
	D: 1										
0/ D	Biodeg			,		.		F 1 .:		N.1	
% Degr			Time (day		NI - :	Method		Evaluation			ote
No infor available			nilable	mation		No information Ivailable		lo information vailable	No informatio available		
12.3.	Bioacc	umula	tive potentia	al							
_	Octano	ol-wate	er partition o	oefficien	t (log	Kow)					
Value		Conce	entration	рН	°C	Method		Evaluati	on	Ī	Vote
-		lo ir vailabl	nformation e	-	-	No information	on	No informatavailable	tion	-	
	Biocon	centra	tion factor (BCF)							
	مباد		Spaci			Mathad		Evaluation			loto

Method

Evaluation

Note



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Product co	ame:		BLUING REAGENT								
Product co	ode: E	3R-OT-X**	D	ate of co	mpila	tion:	23 Jan	uary 20	23	Ve	rsion: 7
No informa available		No inform vailable	ation	No informavailable		1	No info	ormation le		No info	
:	ronic ecot	oxicity	Fxn	osure				8 H			
Value Dose		Dose		ime	Spe	cies	Met	hod	Eva	luation	Note
Chronic toxicity on fish LC ₅₀		No infor availa	mation	No inform availak		No informa availab		No inforr availa	nation ble	-	
Chronic toxicity on crustacea (<i>Daphnia</i>) EC ₅₀		No infor availa	mation	No inform availat		No informa availab		No inforr availa	nation ble	-	
12.4. Mo	obility in s	oil									
	•	edicted distributi	on in e	environme	ntal co	mpart	ments:				
No	o informat	ion available									
Su	rface tens	ion:						T			
	Value	°C				Method		Note			
	ormation ailable	No information available				on No info available		formation ble			
Ad	lsorption /	desorption									
Transport		ocoefficient ry's constant	lc	g Kow	Eva	porati	on rate	Me	ethod		Note
Soil-water	No availabl	information e	No ir availa	nformation able		inform ilable	nation	No info		on -	
	No availabl	information e	No ir availa	nformation able		inform ilable	nation	No info		on -	
Water-air		No information available						No info	No information - available		



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

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Trading name:		BLUING REAGENT									
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7							
Troduct code.	DIC OT X	Date of compliation.	25 January 2025	version. 7							

12.6.	Endocrine disrupting properties					
	No known endocrine disrupting properties that affect the environment.					
12.7.	Other adverse effects					
	No adverse effects are expected.					
SECTIO	N 13. Disposal considerations					
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposal:					
	Submit for disposal to the legal per Protection.	son authorized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste designations ac	cording to Law:				
	No information available					
13.1.3.	Waste treatment – relevant informa	tion:				
	No information available					
13.1.4.	Sewage disposal – relevant informa					
	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:					
	-					
SECTIO	SECTION 14. Transport information					
	Transporting/shipment by road (ADR)					
UN num	nber: No	t subject to transport regulations.				
UN prop	per shipping name: -					
Transpo	ort hazard class(es):					



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Trading name:		BLUING REAGENT				
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version:	7	
Packing group:		-				
Environmentally haz		-				
Special precautions		-				
<u> </u>	ng/shipment by rai					
UN number:		Not subject to transport	regulations.			
UN proper shipping	ı name:	-				
Transport hazard cla	ass(es):	-				
Packing group:		-				
Environmentally haz	zardous:	-				
Special precautions	for user:	-				
Inland wate	erway transport (A	DN)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	name:	-				
Transport hazard cla	ass(es):	-				
Packing group:		-				
Environmentally haz	zardous:	-				
Special precautions	for user:	-				
Transportir	ng/shipment by se	a (IMDG)				
UN number:		Not subject to transport	regulations.			
UN proper shipping	ı name:	-				
Transport hazard cla	ass(es):	-				
Packing group:		-				
Environmentally haz	zardous:	-				
Special precautions		-				
		· (ICAO-TI/IATA-DGR)				
UN number:	-	Not subject to transport	regulations.			
UN proper shipping name:						
Transport hazard class(es):		-				
Packing group:		-				
Environmentally haz	zardous:	-				



amended by Regulation (EU) No. 2020/878

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Trading name:	BLUING REAGENT					
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7		

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

SECTIO	SECTION 16. Other information				
16.1.	Indication of changes:	-			
		PBT	Stable, bioaccumulative and toxic		
		vPvB	Strongly stable and strongly bioaccumulative.		
16.2.	Abbreviations and acronyms:	LD ₅₀	Lethal dose, 50%		
		LC ₅₀	Lethal concentration, 50%		
		STOT-SE	Specific target organ toxicity - single exposure		
16.3.	Key literature references and source of data:	_			



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Trading name:	BLUING REAGENT					
Product code:	BR-OT-X**	Date of compilation: 23 January 2023	Version: 7			

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

ANNEX: Exposure scenario resulting to Chemical safety assessment



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Trading name:	HEMATOXYLIN ML					
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9	

SECTION	ON 1: Identification of	the substance	e/mixture a	and of the company/undertaking	
1.1.	Product identifier	Product identifier			
	Trading name:	HEMATOXYLIN ML			
	Chemical name:	-			
	Catalogue number:	HEMML-O	Γ-X**		
1.2.	Relevant identified us	es of the subs	tance or m	ixture and uses advised against	
	Uses:		Modified	hematoxylin acc. to Mayer-Lillie for nuclear staining.	
	Uses advised against:		Only the	identified uses are advised.	
	Reason why uses advised against:		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes		
1.3.	Details of the supplier	Details of the supplier of the safety data sheet			
	Supplier: Bio		oGnost Ltd.		
	Address:	M	1edjugorska 59, Zagreb		
	Telephone number:	+3	385 1 2409997		
	Fax no.:	+3	-385 1 2404039		
	e-mail of competent p	oerson: <u>m</u>	nsds@biognost.hr		
	National contact:	National contact: -			
1.4.	Emergency telephone	Emergency telephone number			
	National Protection a	National Protection and Rescue Dire		112	
	Medical information:			+385 1 2348 342	
	Other information:				

SECTIO	CTION 2. Hazards identification					
2.1.	Classification of the substance or	Classification of the substance or mixture				
2.1.1.	Classification according to Regul	ation (EC) No 1272/20	08 (CLP)			
	Hazard class and cate	gory code:	Hazard statements*:			
	Eye Irr. 2 H319					
2.1.2.	Additional information					
	-					
*For ful	l text of Hazard- and EU Hazard-sta	atements: see Section	16			
2.2.	Label elements					
	Product identification: HEMATOXYLIN ML					
	Identification number:	Identification number: -				
	Authorization no.:					



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Trading name:	HEMATOXYLIN ML						
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9		

	Hazard pictograms:	GHS07
	Signal word:	Warning
	Hazard statements:	H319 Causes serious eye irritation.
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	Endocrine Disrupting Proper No known endocrine disruptin Results of PBT and vPvB asso PBT or a vPvB.	

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)				
7784-31-8/ 616-524-3/	-	3 – 4 %	aluminum sulfate octadecahydrate	Eye Dam. 1; H318				

SECTION 4. First aid measures				
4.1.	Description of first aid meas	ures		
	General notes:	Take off contaminated clothing.		
	Following inhalation:	Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.		
	Following skin contact:	Rinse skin with water/shower. In all cases of doubt, or when symptoms persist, seek medical advice.		
	Following eye contact:	In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.		
	Following ingestion:	Rinse mouth. Call a doctor if you feel unwell.		



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Trading name:	HEMATOXYLIN ML					
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9	

	Self-protection of the first aider: Treat symptomatically.				
4.2.	Most important symptoms and effects, both acute and delayed				
	Following inhalation: No information available				
	Following skin contact: No information available				
	Following eye contact: Risk of blindness, Risk of serious damage to eyes. Following ingestion: No information available				
4.3.	Indication of any immediate medical attention and special treatment needed				
	-	-			

SECTIO	SECTION 5. Firefighting measures				
5.1.	Extinguishing media				
	Suitable extinguishing media:	Small fire - water spray, dry powder, foam, 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				
	Do not enter fire area without pro	oper protective equipment, including respiratory protection.			
5.4.	Additional information				
	Remove sources of heat and ignit Do not contaminate the environm				

SECTIO	SECTION 6. Accidental release measures				
6.1.	Personal precautions, protective ed	quipment and emergency procedures			
6.1.1.	For non-emergency personnel				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods: Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.				
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:				
	Do not enter fire area without prop	per protective equipment, including respiratory protection.			
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 containr	nent and cleaning up			



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Trading name:	HEMATOXYLIN ML					
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9	

6.3.1.	Bunding, covering of drains; capping procedures:	Covering of drains. Take up mechanically.			
6.3.2.	Cleaning up:	Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. On land, sweep or shovel into suitable containers. 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:	Place in appropriate containers for disposal.			
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	on about containment.			

SECTIO	SECTION 7. Handling and storage						
7.1.	Precautions for safe handling						
7.1.1.	. Protection measures						
	Measures to prevent fire:		Keep away from sources of heat and ignition. Do not smoke.				
	Measures to prevent aerosol and dust generat	ion:	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 inco	mpatibilit	ties				
	Technical measures and storage conditions:		tightly closed and upright set containers in a well ed place.				
	Packaging materials:	Manufa	cturer's original packaging.				
	Requirements for storage rooms and vessels:	Keep av	vay from food and drink. Keep the containers closed.				
	Advices for storage equipment:	be resis	rage must be made of hard material; floors must tant to chemicals. There must be no drain that leads into sewage system. Secure proper ion.				
	Further information on storage conditions:	and do	place the unused material in the storage room not use empty containers for storing other als. Do not store with incompatible materials (see 9).				
7.3.	Specific end use(s)						



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Trading nam	ıe:	HEMATOXYLIN ML					
Product cod	e: HEMMI	1L-OT-X** Revision da		date:	27.03.2023.	Version:	9
	ommendations: Istrial sector spe			_			
	Exposure contr		protection				
Substance CAS No			•	l exposure limit rt term values	Biological limi	t values	
-		_	ppr	ppm mg/m³		No information av	ailable
Substance				l		1	
Substance name: Aluminium sulphate octadecahydrate							

EC No: **DNEL**

		Industrial			
oute of	Acute	Acute			

CAS No:

233-135-0

Route of	Acute	Acute	Chronic	Chronic
exposure:	effect local	effect systemic	effect local	effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	13,4 mg/m ³
Dermal	-	-	-	3,8 mg/kg bw/day

7784-31-8

Critical physical parameters: solubility, flammability, corrosivity:

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available



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Trading name:		HEMAT	OXYLIN ML		
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9

Air			No information available			
8.2.	Exposure controls					
8.2.1.	Engineering measures					
	Substance/mixture related measures to prevent exposure during identified uses: Structural measures to prevent exposure: Organisational measures to prevent exposure:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
			No information available			
			Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equi	pment				
8.2.2.1.	Eye and face protection:		Safety glasses that stick to face (preventing splashing) (EN 166) or visor.			
8.2.2.2.	Skin protection					
8.2.2.2.	Chem 374. Hand protection:		mical protection gloves are suitable, which are tested according to EN. Glove material: nitrile rubber Glove thickness: > 0.11 mm Break through time: >480 min			
	Other skin protection:		es (EN 13034), and shoes that cover the entire foot (EN 10335).			
8.2.2.3.	Respiratory protection:	In cas	se of inadequate ventilation wear respiratory protection.			
8.2.2.4.	Thermal hazards:	No ir	formation available			
8.2.3.	Environmental exposure	control	s			
	Substance/mixture relate measures to prevent exp		See Section 6			
	Structural measures to perfect the exposure:	revent	Use modern equipment.			
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace. Keep away from drains, surface and ground water.			
	Technical measures to pr exposure:	event	See Section 6			

SECTIO	CTION 9. Physical and chemical properties				
9.1.	Information on basic physical and chemical properties				
	Value Method				



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Trading name:		HEMATOXYLIN ML				
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Physical state:	liquid	No information available
Color:	dark red	No information available
Odour/odour threshold:	glycerol 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
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
Other information		

SECTIO	ON 10.: Stability and reactivity	
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
10.6.	Hazardous decomposition products:	No information available.

SECTIO	ON 11. Toxicological information
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008
	Acute toxicity:



Dermal exposure:

No information available

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

Route of exposure: Oral exposure: Inhalation exposure: Specific target org Oral exposure: No Oral exposure: No Respiratory irritation and correct	Method ydrous (ECHA) ydrous (ECHA) information available	Revision date: Species rabbit rat	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture} LD ₅₀	D23.	>2.000-<5.000 mg/kg (aluminium sulphate octadecahydrate)
Route of exposure: Oral exposure: Inhalation exposure: Specific target org Oral exposure: No Oral exposure: No Respiratory irritation and correct	Method ydrous (ECHA) ydrous (ECHA) o information	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture} LD ₅₀	Exposu	Results >2.000-<5.000 mg/kg (aluminium sulphate octadecahydrate)
Oral exposure: Dermal exposure: Inhalation exposure: Specific target org Oral exposure: No Dermal exposure: No Respiratory irritation Irritation and corre	ydrous (ECHA) ydrous (ECHA) o information	rabbit	dose LD ₅₀ /LC ₅₀ or ATE _{mixture} LD ₅₀	•	>2.000-<5.000 mg/kg (aluminium sulphate octadecahydrate)
Dermal exposure: anhy Inhalation No exposure: Specific target org Oral exposure: No Dermal exposure: No Inhalation exposure: No Respiratory irritation	ydrous (ECHA) o information			-	(aluminium sulphate octadecahydrate)
Inhalation exposure: Specific target org Oral exposure: No Dermal exposure: Inhalation exposure: Respiratory irritation Irritation and corre	information	rat	LD ₅₀		. г 000 //
Specific target org Oral exposure: Dermal exposure: Inhalation exposure: Respiratory irritation Irritation and corre				-	>5.000mg/kg (aluminium sulphate octadecahydrate)
Oral exposure: No Dermal exposure: No Inhalation exposure: No Respiratory irritation Irritation and corre		-	LC ₅₀	-	-
Oral exposure: No Dermal exposure: No Inhalation exposure: No Respiratory irritation Irritation and corre	an toxicity – single	e exposure (STOT S	E):		
Dermal exposure: No Inhalation exposure: No Respiratory irritation	Specific 6	·		et organ	Note
Respiratory irritation	Oral exposure: No information ava		No information available		-
Respiratory irritation	o information avail	No information available		-	
Irritation and corro	o information avail	able No information available		-	
	on:	No information av	vailable		
	osion				
	exposure time	Species	Evaluati on	Meth od	Note
Skin irritation: -		-	-	_	
Eye irritation: -		-		- (Causes serious eye damage
Sensitization					
Dermal exposure: No info	ormation available				
Inhalation exposure:	ormation available				
Symptoms related	to the physical cl	hemical and toxicol	ogical char	acteristics	
Oral exposure: No	to the physical, ci		ogical chare	201131103	



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Trading name:		HEMAT	OXYLIN ML		
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9

Eye exposure:	Causes serio	us eye damage	9				
Reneat	ed dose toxicity (su	hacute subchr	onic chronic)				
Кереис	Dose Dose	Exposure time	Species	Method	Evaluation	າ	Note
Subacute oral	No information available	No information available	No information available	No information available	No inform available	nation	-
Subacute dermal	No information available	No information available	No information available	No information available	No inform available	nation	-
Subacute inhalation	No information available	No information available	No information available	No information available	No inform available	nation	-
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 inform available	nation	-
Chronic oral	No information available	No information available	No information available	No information available	No inform available	nation	-
Chronic dermal	No information available	No information available	No information available	No information available	No inform available	nation	-
Chronic No information inhalation available		No information available	No information available	No information available	No inform available	nation	-
Specific	target organ toxic	ty - repeated	evnosure (STO	T RF)·			
эрссии	target organ toxic	Specific effect	•	-	gan		Note
Subacute oral	No informa	ation available		Target organ No information available		-	
Subacute derma		ation available		No information available		-	
Subacute inhalat		ation available		No information		-	
Subchronic oral		ation available				_	



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Trading name:		HEMAT	OXYLIN ML		
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9

Subchro	nic dermal	No information availa	able	No information available	-		
Subchro	nic inhalation	No information availa	able	No information available	-		
Chronic	oral	No information availa	able	No information available	-		
Chronic	dermal	No information availa	able	No information available	-		
Chronic	inhalation	No information availa	able	No information available	-		
***	CMR effects (c	carcinogenicity, mutage	enicity reproducti	ve toxicity)			
	Carcinogenicit	3 , 3	No information a				
	Mutagenicity (No information available				
	Genotoxicity:		No information available				
	Mutagenicity	in-vivo:	No information available				
	Germ cell mut	agenicity:	No information available				
	Reproductive	toxicity:	No information a	vailable			
	Summary of e	valuation of the CMR p	roperties:	-			
44.0							
11.2.	Information on other hazards:						
11.2.1.	Endocrine disr	rupting properties:					
	No known properties tha	endocrine disrupti t affect human health.	ng				
11.2.2.	Other informa	tion:					
	_						

SECTION 12. Ecolog	ical inforn	nation				
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Fish	ECHA	>85.9 mg/l (aluminium sulphate octadecahydrate)	-
Crustacea:	EC ₅₀	48 hours	aquatic invertebrates	ECHA	>200 mg/l (aluminium sulphate octadecahydrate)	-
Algae/aquatic plants	IC ₅₀	8 days	algae	No information available	-	-



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Trading name:		НЕМАТ	OXYLIN ML		
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9

Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	_
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	_
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	_
Other organisms	EC ₅₀	180 min	microorganisms	ECHA	>1.000 mg/l (aluminium sulphate octadecahydrate)	-

12.2. Persistence and degradability

Abiotic degradation

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

Biodegradation

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

12.3. Bioaccumulative potential

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

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



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Trading name:		HEMAT	OXYLIN ML		
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9

V	'alue		Species		Meth	nod	Eva	luation		No	te
No info availabl	rmation le	No ava	inforn ailable	nation	No inforr available		No information available			No information available	
	Chronic	ecoto	xicity								
	Value		Dose		osure me	Species	Meth	od	Eva	lluation	Note
Chronic	toxicity o	on fish	LC ₅₀	No inforr availa	nation io	No nformat on vailable	No inform available	ation	No info	ormation le	-
	toxicity of ea (<i>Daphr</i>		EC ₅₀	No inforr availa	nation io	No nformat on vailable	No inform	ation	No info	ormation le	-
12.4.		or pre	il dicted distribut on available	ion in e	environme	ntal com _l	partments:				
	Surface	tensic	n:								
	Valu	ıe	°C		Concen	tration	Meth	od		Note	
	No informa availabl		No inform available	nation	No inforr available	mation	No inform available	ation	_		
	Adsorp	tion / o	desorption								
Transpo	ort		coefficient 's constant	lo	g Kow	Evapo	ration rate	М	ethod		Note
Soil-wa	ter No	ailable	information	No in availa	formation ble	No info	ormation lle	No inf	ormation ole	-	
Water-a	air No	ailable	information	No in availa	formation ble	No info	ormation lle	No inf availat	ormation ole	-	
	No		information		formation	1	ormation		ormation		



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Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9

12.5.	Results of PBT and vPvB assessment
	No information available
12.6.	Endocrine disrupting properties
	No known endocrine disrupting properties that affect the environment.
12.7.	Other adverse effects
	No adverse effects are expected.
SECTIOI	N 13. Disposal considerations
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-
	N 14. Transport information



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Trading name:	HEMATOXYLIN ML				
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UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by r	rail (RID)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by s	sea (IMDG)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by a	air (ICAO-TI/IATA-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-



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Trading name:	HEMATOXYLIN ML				
Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9

Further information:	The product is not subject to classification.
	in the production in the company of

15.1.	Safety, health and enviro	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations					
	Authorization and/or rest	trictions 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)	999/13/EC about limitation of emissions of volatile organic compounds (VOC-				
	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values are National legislation: 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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Product code:	HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9

16.2.	Abbreviations and acronyms	par route (European Dangerous Goods by IMDG: International MIATA: International MIATA: International MIATA: GHS: Globally HIATA: GHS: Globally HIATA: EINECS: European Invited CAS: Chemical Abstruction DNEL: Derived No-ELC50: Lethal concert LD50: Lethal dose, Support Persistent, Biomannian Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal dose, Support Persistent, Biomannian Daniel (European Invited No-ELC50) Lethal (European Invited No-ELC50) L	Maritime Code for Dangerous Goods Air Transport Association armonised System of Classification and Labelling of rentory of Existing Commercial Chemical Substances racts Service (division of the American Chemical Society) iffect Level (UK REACH) intration, 50 percent	
16.3.	Key literature references and source of data:	-		
16.4.	Classification and procedure 1272/2008 (CLP)	d to derive the classifica	ntion for mixture according to Regulation (EC)	
Classific	cation	ssification procedure		
-		-		
16.5.	Relevant H statements (num	and full text)		
	H: 318	uses serious eye damage	e.	
	319	uses serious eye irritatio	n.	
16.6.	Training advice:	-		
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

ANNEX: Exposure scenario resulting to Chemical safety assessment



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

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Trading name:	PERIODIC ACID, 0.8 % SOLUTION				
Product code:	PK08-OT-X**	Date of compilation:	21 Dec 2022	Version: 4	

SECTI	ON 1 IDENTIFICATION	OF THE SUB	STANCE/MI	XTURE AND OF THE COMPANY/UNDERTAKING	
1.1.	Product identifier				
	Trading name:	PERIODIC	ACID, 0.8 %	SOLUTION	
	Chemical name:	-			
	Catalogue number:	PK08-OT-	X**		
1.2.	1.2. Relevant identified uses of the substance or mixture and uses advised against			xture and uses advised against	
	Uses:		For use wi	ith special staining kits.	
	Uses advised against:		Only the i	dentified uses are advised.	
	Reason why uses advis	sed 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	y data sheet		
	Supplier:	E	BioGnost Ltd.		
	Address:	1	Medjugorska 59, Zagreb +385 1 2409997 +385 1 2404039		
	Telephone number:	-			
	Fax no.:	-			
	e-mail of competent p	erson: <u>r</u>	msds@biognost.hr		
	National contact:	National contact: -			
1.4.	Emergency telephone	Emergency telephone number			
	National Protection ar	nd Rescue Di	rectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	CTION 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*:						
	Not identified as hazardous subst	-					
2.1.2.	Additional information						
	-						
*For fu	ll text of Hazard- and EU Hazard-sta	atements: see S	ection 16				
2.2.	Classification according to EC Dire	ective Nr. 1272	/2008 CLP)				
	Product identification:	PERIODIC AC	ID, 0.8 % SOLUTION				
	Identification number: -						
	Authorization no.:	-					
	Hazard pictograms:	-					



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Trading name:	PERIODIC ACID, 0.8 % SOLUTION			
Product code:	PK08-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

	Signal word:	-
	Hazard statements:	-
	Precautionary statements:	-
	Further information:	-
2.3.	Other hazards	
	Endocrine Disrupting Proper	ties:
	No known endocrine disruptin	ng properties
	Results of PBT and vPvB asserts or a vPvB.	essment : According to the results of its assessment, this substance is not a

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)	
-	-	-	-	-	

SECTI	ION 4 FIRST AID MEASURES				
4.1.	Description of first aid measu	res			
	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.			
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 aid	Treat symptomatically.			
4.2.	Most important symptoms an	nd effects, both acute and delayed			
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.			
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Longterm exposure may cause drying, cracking and tingling sensation of skin.			



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Trading name:	PERIODIC ACID, 0.8 % SOLUTION			
Product code:	PK08-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.
	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.
4.3.	Indication of any immedia	te medical attention and special treatment needed
	-	

SECTIO	ECTION 5 FIREFIGHTING MEASURES			
5.1.	Extinguishing media			
	Suitable extinguishing media:	spray, dry powder, CO ₂ 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 a	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 extinguish	ing media.		

SECTIO	ECTION 6 ACCIDENTAL RELEASE MEASURES			
6.1.	Personal precautions, protective equipment and emergency procedures			
6.1.1.	For non-emergency personnel			
	Protective equipment: Use personal protective equipment (see Section 8).			
	Accident prevention methods: Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.			
	Emergency procedures:	Mark the area using proper signs.		
6.1.2.	For emergency responders:			
	Wear protective equipment (see Section 8).			
6.2.	Environmental precautions:			
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.			
6.3.	Methods and material for containme	nt and cleaning up		



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Product code:	PK08-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

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	
	-	

SECTIO	ON 7 HANDLING AN STORAGE			
7.1.	Precautions for safe handling			
7.1.1.	Protection measures			
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.		
	Measures to prevent aerosol and dust generat	ion: Secure proper ventilation.		
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.		
	Other measures:	-		
7.1.2.	.2. Advice on general occupational hygiene:			
	Do not eat, drink or smoke in the workspace. T	Thoroughly 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:	Keen away from food and drink Keen the containers		
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.		
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).		
7.3.	Specific end use(s)			



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Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8 EX			TROLS/PER	SONAL	PROT	ECTION			
i i	rol para	meters	CAS N	No			exposure lim term values		iological limit values
						ppm	mg/m³		J
-			-			-	-	No info	ormation available
Substance name:	-								
EC No:	-		CAS No:	_					
DNEL									
					Inc	dustrial			
Route of exposure:			Acute ect local	effe	Acutect sys		Chronic effect local		Chronic effect systemic
Oral		-		-			-		-
Inhalation		-		-			-		-
Dermal		-		-			-		-
Critical physic	al parar	neters: s	solubility, fla	mmabili	ty, cor	rosivity:	_		
					Co	nsumer			
Route of exposure:			Acute ect local	effe	Acutect sys			ronic et local	Chronic effect systemic
Oral		-		-			-		-
Inhalation		-		-			-		-
Dermal		-		-			-		-
PNEC									
Environmenta	l protec	tion tar	get			PNEC			
Fresh water						No information available			
Freshwater sediments			No information available						
Marine water			No information available						
Marine sediments				No information available					
Food chain			No information available						
Microorganis	ms in se	wage tr	eatment			No information available			
Soil (agricultu	ral)					No information available			



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Trading name:		PERIODIC ACID, 0.8 % SOLUTION					
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Air			No information available				
8.2.	Exposure controls						
8.2.1.	Engineering measures						
	Substance/mixture relate measures to prevent expeduring identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.				
	Structural measures to preserve:	revent	No information available				
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.				
	Technical measures to pr exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.				
8.2.2.	Personal protection equi	Personal protection equipment					
8.2.2.1.	Eye and face protection:	rotection: Safety glasses that stick to face (preventing splashivisor.					
8.2.2.2.	Skin protection						
O.E.E.E.	Hand protection:		otective gloves must be according to the EU Directive 2016/425/EEC and ndard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min				
	Other skin protection:		ar antistatic clothing made of natural fibers (such as cotton) with long ves (EN 13034), and shoes that cover the entire foot (EN 10335).				
8.2.2.3.	Respiratory protection:	filter f	ctive full face mask (EN 136) or half mask (EN 140) equipped with a cor organic vapors, type "A" (boiling point >65°C) acording to EN) used when concentration levels exceed GVI.				
8.2.2.4.	Thermal hazards:	No inf	ormation available				
8.2.3.	Environmental exposure	controls					
	Substance/mixture relate measures to prevent exp		See Section 6				
	Structural measures to preserve:	revent	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



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Trading name:	PERIODIC ACID, 0.8 % SOLUTION					
Product code:	PK08-OT-X**	Date of compilation:	21 Dec 2022	Version: 4		

	Value	Method
Physical state:	liquid	No information available
Colour:	colourless	No information available
Odour/odour threshold:	no odor/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
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

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.				

SECTION 11 TOXICOLOGICAL INFORMATION



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Trading name:		PERIODIC ACID, 0.8 % SOLUTION					
Product code:	PK08-OT-X**	Date of compilation:	21 Dec 2022	Version:	4		

A cuto tovi	city:						
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposu	re time	Results	
Oral exposure:	No information available	_	LD ₅₀		_	_	
Dermal exposure:	No information available	-	LD ₅₀		_	-	
Inhalation exposure:	No information available	-	LC ₅₀		-	-	
Specific ta	rget organ toxicity – si	nale evnosure (STOT SEI:				
Specific ta	5 5	c effects		t organ		Note	
Oral exposure:	No information a				a –	INOLE	
Dermal exposure:	No information a		No information available - No information available -				
Inhalation exposure				No information available -			
ililialation exposure	. No imormation a		NO IIIIOIIIIati	On available			
Respirator	y irritation:	No infor	mation available				
Respirator	y irritation.	NO IIIIOI	Thation available				
Irritation a	nd corrosion						
	Exposure time	Species	Evaluation	Method		Note	
Skin irritation:	-	rabbit	_	-	-		
Eye irritation:		rabbit	-	_	-		
		<u> </u>		<u> </u>	<u> </u>		
Sensitization	on						
Dermal exposure:	No information availa	able					
Inhalation exposure:	No information availa	able					
	İ						
Symptoms	related to the physica	l, chemical and	toxicological char	acteristics			
Oral exposure:	Swallowing may consensation; higher lin case of vomiting	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.					
Dermal exposure:	Slight irritation. Af may cause drying,	ter short expos	ure, resorption eff		likely. Lor	ng-term exposure	



SAFETY DATA SHEET ding to Regulation (EC) No. 1907/2

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Inhalation exposi	ure:		large amounts eezing, heada			idequately vent	ilated perime	eter may cause
Eye exposure: Direct eye co sensation.			ontact may cause slight to moderate irritation, lacrimation and burning					
Repeate	ed dose	e toxicity (sub	acute, subchro	onic, chroni	c)			
		Dose	Exposure time	Species		Method	Evaluation	Note
Subacute oral	No availa	information able	No information available	No informati available	on	No information available	No informatio available	n -
Subacute dermal	No availa	information able	No information available	No informati available	on	No information available	No informatic available	on -
Subacute inhalation	No information available		No information available	No informati available	on	No information available	No informatio available	on -
Subchronic oral	No information available		No information available	No informati available	on	No information available	No informatic available	n -
Subchronic dermal	No information available		No information available	No informati available	on	No No information information available available		n -
Subchronic inhalation	No information available		No information available	No informati available	on	No information available	No informatic available	n -
Chronic oral	No availa	information able	No information available	No informati available	on	No information available	No informatic available	n -
Chronic dermal	No availa	information able	No information available	No informati available	on	No information available	No informatio available	n -
Chronic inhalation			No information available	No informati available	on	No information available	No informatic available	n -
Specific	target		y – repeated e	xposure (S	IOT R			Nata
Subacute oral			pecific effects tion available		Target organ No information available			Note
Subacute orai Subacute dermal			tion available			nformation avai		-
Subacute inhalat			tion available			nformation avai		<u>-</u>



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Subchronic oral No information		n available	No information available	-	
Subchronic dermal	No information	available	No information available	-	
Subchronic 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	-	
		<u> </u>	oductive toxicity)	urcinogonic offocts	
Carcinogenicit	-	Current studies on test animals did not indicate carcinogenic effects.			
Mutagenicity i	n-vitro:	Current <i>in vitr</i>	o tests did not indicate mutageni	c effects.	
Genotoxicity:		No information	available		
	n-vivo:	Current in vivo tests did not indicate mutagenic effects.			
Mutagenicity i	// VIVO.		<u> </u>		
Mutagenicity i		No information			

Summary of evaluation of the CMR properties:	_
carriery or evaluation of the crimit properties.	

11.2 Information on other hazards:

11.2.1. Endocrine disrupting properties:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

11.2.2. Other information:

-

SECTION 12 ECOLOGICAL INFORMATION:											
12.1. Toxicity											
Acute toxicity	Acute toxicity Dose Exposure time Species Method Evaluation Note										
Fish	LC ₅₀	96 hours	No information available	No information available	-	-					



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	!	i							

Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	_	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2. P	Persistence and	d dearadab	ilitv
---------	-----------------	------------	-------

Abiotic degradation

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

Biodegradation

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

12.3.	12.3. Bioaccumulative potential										
	Partition coefficient: n-octanol/water (log Kow):										
Valu	Value Concentration pH °C Method Evaluation Note										



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Trading	name:				PER	IODIC	ACID,	0.8 %	6 SOLUT	ΓΙΟΝ		
Product	t code:	PK08-	-OT-X**		Date	of co	mpilatio	on:	21 Dec	2022	Versio	on: 4
-	No avail	inform able	nation _		_	No info	ormation le		lo inform vailable	ation	-	
	D:		ft /DCF									
	alue	ntration	factor (BCF Species)	ı	/lethod	1		Evaluatio	nn.		Note
No infor available	mation	No availat	inforn	nation	No info	rmatic		Evaluation No information available		No inform		
	Chronic e	cotoxicit	ту									
	Value		Dose		osure ime	Spe	ecies	М	ethod	Eva	luation	Note
Chronic ·	toxicity or	n fish	LC ₅₀	No infor avail	mation able	No infori availa	mation able	No infor avail	mation able		lo information -	
	toxicity or a (<i>Daphni</i>		EC ₅₀	No infor avail	mation able	No infori availa	mation able	No infor avail	mation able	No info	o information	
12.4.	Mobility i	n soil										
	•		ed distribut	ion in e	environm	ental o	comparti	ments	: :			
	No inforn	nation av	/ailable									
	Surface to	ension:										
	Value		°C	С	oncentra	tion		Met	hod		N	ote
	No information available		ormation ailable		No information available		No info	ormation ble		-	-	
	Adsorptic	on / desc	orption									
Transpor	rt	A/D coef lenry's co	ficient	lo	og Kow	E۱	/aporatio	on rat	e ſ	Method		Note
Soil-wate	er No avail		nformation	No ir availa	nformatic able		o inform ailable	ation	No ir	nformation able	on -	



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Trading name: PERIODIC ACID, 0.8 % SOLUTION								
Produc	t cod	e: P	K08-OT-X**	Date of	compilation:	21 Dec 2022	Version: 4	
Water-a	er-air No information available			No information available	No information available	No information available	-	
Soil-air		No available	information	No information available	No information available	No information available	-	
12.5	Dogu	lts of DD.	Tand vDvD asse	-cm ont				
12.5.			T and vPvB asses			l de la compania de compania de la compania del compania del compania de la compania del compania de la compania de la compania del la compania del compania del compania del compania del compania del compania de	-1:	
	accoi	rding to	REACH Article 5		n Delegated regul	ation (EU) 2017/210	disrupting properties 0 or Commission	
12.6.			rupting propert					
	accoi	rding to	REACH Article 5	· ·	n Delegated regul	to have endocrine ation (EU) 2017/210	disrupting properties 0 or Commission	
12.7.	Othe	r adverse	e effects					
	No ir	nformatio	on available					
SECTIO	N 13 I	DISPOSA	AL CONSIDERA	TIONS				
13.1.	Wa	ste treat	ment methods					
	:							
13.1.1.	Pro	duct/Pa	ckaging disposa	l:				
		omit for otection.	disposal to the l	egal person autho	rized by the Minis	try of Environmenta	ll and Nature	
13.1.2.	\\/a	esto soda	es huasta dasigna	tions asserding to	- L			
13.1.2.			tion available	tions according to	D Law.			
	INO	IIIIOIIIIa	tion available					
13.1.3.	Wa	ste treat	ment – relevant	information:				
	No	informa	tion available					
13.1.4.	Sev	wage dis	posal – relevant	information:				
	Wa	ste must	t not be dispose	d of into the sewa	ge system.			
13.1.5.	Oth	ner dispo	sal recommend	ations:				



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	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:
	-	
SECTIO	N 14 TRANSPORT INFORI	MATION
	Transporting/shipment by	road (ADR)
UN num	nber:	Not subject to transport regulations.
UN pro	per shipping name:	-
Transpo	ort hazard class(es):	-
Packing	group:	-
Environ	mentally hazardous:	-
Special	precautions for user:	-
	Transporting/shipment by	rail (RID)
UN number:		Not subject to transport regulations.
UN pro	per shipping name:	-
Transpo	ort hazard class(es):	-
Packing	group:	-
Environ	mentally hazardous:	-
Special	precautions for user:	-
	Inland waterway transport	(ADN)
UN num	nber:	Not subject to transport regulations.
UN pro	per shipping name:	-
Transpo	ort hazard class(es):	-
Packing	group:	-
Environ	mentally hazardous:	-
Special	precautions for user:	-
	Transporting/shipment by	sea (IMDG)
UN num	nber:	Not subject to transport regulations.
UN pro	per shipping name:	-
Transpo	ort hazard class(es):	-
Packing	group:	-
Environ	mentally hazardous:	-
Special	precautions for user:	-



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Trading name:	PERIODIC ACID, 0.8 % SOLUTION			
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UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

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



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None

SECTIO	SECTION 16 Other information			
16.1.	Indication of changes:	-		
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative		
16.3.	Key literature references and source of data:	-		
16.4.	4. Classification and procedure used to derive the classification for mixture according to Regulation (EC)			
Classification		Classification procedure		
-		-		
16.5.	.5. Relevant H statements (number and full text)			
	H: -	-		
16.6.	Training advice:	-		
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

ANNEX:

Exposure scenario resulting to Chemical safety assessment

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