

P.A.S. DIASTASE KIT

The kit contains:

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



Page 1 of 17

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

SECTION	ON 1: Identification of t	he su	ıbstance/mixture a	nd of the company/undertaking	
1.1.	Product identifier				
	Trade name:	ALF	ALPHA-AMYLASE, SOLUTION		
	Chemical name:	-	-		
	Catalogue number:	ALF	-OT-X**		
1.2.	Relevant identified use	es of t	he substance or mix	ture and uses advised against	
	Uses:		For differentiation	between glycogen and P.A.Spositive structures	
	Uses advised against:		Only the identified	uses are advised.	
	Reason wny uses advised		The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.		
1.3.	Details of the supplier	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:		+385 1 240403	+385 1 2404039	
	e-mail of competent person:		ı: <u>msds@biogno</u>	msds@biognost.hr	
	National contact:		-	-	
1.4.	Emergency telephone	Emergency telephone numbers			
	National Protection ar	nd Res	scue 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 Re	gulation (EC) No 1	272/2008 (CLP)		
	Hazard class and cate	egory code:	Warning statements*:		
	Respiratory sensitisation. Category 1 H334				
2.1.2.	Additional information				
	-				
* For fu	ull text of Hazard- and EU Hazar	d-statements: see	SECTION 16		
2.2.	Label elements				
	Product identification: ALPHA-AMYLASE, SOLUTION				
	Identification number:	-			
	Authorisation number:	-			



Page 2 of 17

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

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. 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	

SECTIO	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.			



Page 3 of 17

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

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

SECTIO	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 substance 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 apparatus for firefighting if necessary.				
5.4.	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.			



Page 4 of 17

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

			p	
	Emergency procedures:		Evacuate personnel to safe areas. For personal protection see section 8.	
6.1.2.	For emergency responde	ers:		
	Self-contained open-circ dissipation (fireproof clo	•	ssed air breathing apparatus, a set for protecting the body from heat	
6.2.	Environmental precautio	ns:		
	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	o 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 section	ons		
	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.



PNEC

Fresh water

Environmental protection target

Advices for storage equipment:

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

Page 5 of 17

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

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

	proper ventilation.							
	Further info	mation	ation on storage conditions: -					
7.3.	Specific end	use(s)						
	Recommend	Recommendations: Apart for stipulate			uses mentioned	in section 1.2 n	o other s	oecific uses are
	Industrial se specific solu		-	-				
SECTI	ON 8. Exposur	e contro	ols/persona	l protec	tion			
8.1.	Control para	meters		-				
	Substance		CAS I	No	•	exposure limit term values	Bio	ological limit values
					ppm	mg/m³		
			-		-	-	No	information available
* Sour	rce - material sa	fety dat	a sheet prov	ided by	the raw materia	ls supplier		
Subst	ance: -							
EC No):		CAS No:	-				
DNEL	1							
					Industrial			
Route	of exposure:	Route exposi		Route	of exposure:	Route of expo	osure:	Route of exposure:
Oral		-		-		-		-
Inhala	ition	-		-		-		-
Derma	al	-		-		-		-
Critica	al physical parar	neters: s	olubility, fla	mmabilit	ty, corrosivity:	-		
					Consumer			
Route of exposure: Route of exposure:			Route	of exposure:	Route of expo	osure:	Route of exposure:	
Oral		-		-		-		-
Inhala	ition	-		-		-		-
Derma	al	_				_		l _

PNEC

No information available



Freshwater sediments

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

No information available

Page 6 of 17

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

- I Collwate	a scannents		No information available	
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 control	S		
	Substance/mixture related measures to prevent exposure during identified uses:	protect	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 exposure:		•	ate 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 Section 7.2		
8.2.2.	Personal protection equipment:			
8.2.2.1.	Eye and face protection:	tested a	glasses recommended. Use equipment for eye protection and approved under appropriate government standards NIOSH (US) or EN 166(EU).	
8.2.2.2.	Skin protection			
	Hand protection:	to use. glove's Dispose applica 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 cations of Regulation (EU) 2016/425 and the standard EN rived from it.	
	Other skin protection:	Wear la	ab coat or apron.	
8.2.2.3.	Respiratory protection:	If aerosol formation: wear respiratory mask.		
8.2.2.4.	Thermal hazards:	No information available.		
8.2.3.	Environmental exposure controls	;		
	Substance/mixture related measures to prevent exposure:	See Sec	ction 6	



Page 7 of 17

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

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

Information on basic physical 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
Lover and upper explosion limit:	No information available	No information available
Flash point:	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
pH:	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

SECTION 10.: Stability and reactivity



Page 8 of 17

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

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
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

11.1. Inform	ation on toxicological ef	fects					
Acute ·	toxicity:						
Route of exposure:	Method	Method Species		Effective Dose /LC ₅₀ or ATE _{mixture}	Expos tim	: H	Results
Oral:	No information available	rat	No ir availa	formation able	-	-	
Dermal:	No information available	rabbit		No information available		-	
Inhalation:	No information available	rat	No information available		-	-	
Specifi	c target organ toxicity -	single exposi	ure (STOT	-SE):			
	Specifi	c effects		Target org	an	No	te
Oral:	No information ava	ailable		No information a	vailable	-	
Dermal:	No information ava	ailable		No information available -			
Inhalation:	No information ava	ailable	No information available -				
Aspira	tion hazard:	Insi	ignificant o	danger at normal	handling t	emperature.	
Irritatio	on and corrosion						
:	Exposure	e time	Spec	ies Evaluati	on	Method	Note
Skin corrosion/irritat	ion No information	No information available		Not irritating.	1	information lable	_
Serious eye damage/irritatio	No information	available	rabbit	Not irritating.	not	specified	-



Page 9 of 17

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

Skin sensitization	kin sensitization: No informa								
Respiratory sensitization:	No informa	tion available							
Sympto	ms related to the p	hysical, chemic	al and toxicolog	ical characteristi	cs				
Oral exposure:	No informatio	n available							
Dermal exposure	: In case of prol	onged or frequ	ent skin contact	irritation sympto	oms cannot be e	excluded			
Inhalation exposure:	•	•	ation of enzyme dust caused by improper handling may cause allergic ling asthmatic bronchitis for sensitive persons						
Eye exposure:	No informatio	n available							
;									
Repeate	ed dose toxicity (su	bacute, subchro	onic, chronic)	1	1				
	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 No information dermal 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	-			



Page 10 of 17

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

	Specific target organ tox	icity - repeated (exposure (ST	OT-RE):			
		Specific effects		Target organ	Note		
Subacu	ite oral	No information a	available	No information available	-		
Subacu	ıte dermal	No information a	available	No information available	-		
Subacu	ıte inhalation	No information a	available	No information available	-		
Subchronic oral		No information a	available	No information available	-		
Subchronic dermal		No information a	available	No information available	-		
Subchronic inhalation		No information a	available	No information available	-		
Chronic oral		No information a	available	No information available	-		
Chronic	c dermal	No information a	available	No information available	-		
Chronic	c inhalation	No information a	available	No information available	-		
	Mutagenicity in-vitro: Genotoxicity: Mutagenicity in-vivo: Germ cell mutagenicity: Reproductive toxicity: Summary of evaluation properties; :	of the CMR	No informa No informa No informa No informa	ation available			
11.2.	Information on other haz	zards:					
11.2.1.	Endocrine disrupting pro	perties:					
	No known endocrir properties that affect hu	1 3					
11.2.2.	Other informations:						
	To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.						

Toxicity 12.1.



Page 11 of 17

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

Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish:	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	No information available	No information available	-	-
Other organisms:	-	-	-	-	-	_
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	No information available
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	No information available
			No	No	No	No
Algae/aquatic plants:	IC ₅₀	72 hours	information available	information available	information available	information available

12.2. Persistence and degradability

Time (days)

Abjotic degradation

% 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	-

Method

Evaluation

Note



Page 12 of 17

Trade name				Α	LPHA-A	IMYLA:	SE, SOLUTION				,	
Product cod	le:	ALF-C	DT-X**		Date of co	ompilati	on: 2	1 Dec 2022		Versior	1:	2
		i.		i		•	<u> </u>			1		
No information No infavailable available		inform e	ation	No information available			No information available		No information available			
							i					
12.3. Bioa	accum	ulative p	otential									
				efficien	nt (log Kov	v)						
Value	Value Concentration pH			°C		thod	Evaluatio	n		Note		
No information available			nation -		-	No infor				No information available		on
г.			F /D.	~								
	oncer	ntration	Factor (B			N A - 411		Frahratian			NI - 4 -	
Value		NI= :-f	Species			Method		Evaluation			Note	
No informati available	on	availak	ormation ole		No information available			No information available		No inforr available	natior	1
Chr	onic e	cotoxicit	:у									
Va	lue		Dose	E>	kposure time	Spe	ecies	Method	Eva	aluation		Note
Chronic toxic	ity on	fish	LC ₅₀		rmation lable	No inform availak		No information available	No infor avail	mation able	Not exp	: ected.
Chronic toxic crustacea (Da	-		EC ₅₀		rmation lable	No inform availat		No information available	No infor avail	mation able	Not exp	ected.
12.4. Mol	oility ii	n soil										
Kno	wn or	predicte	ed distrib	ution ii	n environi	mental co	mpartm	nents:				
Surf	ace te	nsion:				<u>, , , , , , , , , , , , , , , , , , , </u>						
	Value		°C		Concentr	ation		Method		N	ote	



Page 13 of 17

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Trade	name	: :			ALPHA-	·AM\	LASE, SOLUTION		
Produc	ct cod	de:	ΑL	F-OT-X**	Date of compila	tion:	21 Dec 2022	Versio	n: 2
									•
		ormatio ilable	n	No information available	No information available		information ilable	-	
	Ads	orption	n / c	lesorption					
Transpo	ort		-	O coefficient ry's constant	log Kow		Evaporation rate	Method	Note
Soil-Wa	-Water No information available		No informa available	tion	No information available	No information available	-		
Water-	ater-Air No information available		No informa available	tion	No information available	No information available	-		
Soil-Air	Soil-Air No information available				No information available	No information available	-		
12.5.	Res	ults of	PBT	and vPvB assessr	ment				
							ered to be either per (vPvB) at levels of 0.		mulative and
12.6.	End	ocrine	disr	upting properties	5				
	acco	ording	to F	REACH Article 57(•	elega	onsidered to have en ted regulation (EU) 2	•	•
12.7.	Oth	er adve	erse	effects					
	No	inform	atio	n available					
SECTIO	N 13	. Dispo	sal	considerations					
13.1.	W	aste tr	eatr	ment methods					
13.1.1.				kaging disposal:					
	ot	ther na	tion	al and local regul		icals i	vith the Directive on in original containers		



Transporting/shipment by rail (RID)

UN number:

Trade name:

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

ALPHA-AMYLASE, SOLUTION

amended by Regulation (EU) No. 2020/878

Page 14 of 17

Product code: ALF-OT-X**		ALF-OT-X**	Date of compilation:	21 Dec 2022	Version:	2						
			·			· ·						
13.1.2.	Waste o	Waste codes/waste designations according to Law:										
	-											
13.1.3.	Waste o	codes/waste designa	ations according to Law:									
		ating the product at stion products.	high temperatures is recom	mended in order to a	void incomplete							
13.1.4.	Sewage disposal – relevant information:											
10.1	Waste must not be disposed of into the sewage system.											
	vvaste .	must not be dispose	d of file the semage system	1.								
13.1.5.	Other o	Other disposal recommendations:										
	-	-										
13.1.6.	Relevar	Relevant Community provisions:										
	-											
SECTIO	N 14. Trai	nsport information										
	Transpor	ting/shipment by ro	ad (ADR)									
UN num	ıber:		Not subject to transpo	rt regulations.								
UN prop	oer shippir	ng name:	-									
Transpo	rt hazard o	class(es):	-									
Packing	group:		-									
Environr	mental haz	zards:	-									
Special r	precaution	ns for user:	-									

UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by	y inland waterways (ADN)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	_

Not subject to transport regulations.



Page 15 of 17

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

Special precautions for user:	-			
Transporting/shipment by sea (IN	Transporting/shipment by sea (IMDG)			
UN number:	Not subject to transport regulations.			
UN proper shipping name:	-			
Transport hazard class(es):	-			
Packing group:	-			
Environmental hazards:	-			
Special precautions for user:	-			
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-			
Transporting/shipment by air (IC	AO-TI/IATA-DGR)			
UN number:	Not subject to transport regulations.			
UN proper shipping name:	-			
Transport hazard class(es):	-			
Packing group:	-			
Environmental hazards:	-			
Special precautions for user:	-			
Further information: -				

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



Page 16 of 17

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

	None	
15.2.	Chemical safety assessme	nt
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
	Information according 199 guideline)	99/13/EC about limitation of emissions of volatile organic compounds (VOC-
	Other EU regulations:	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 XVIII);
		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;

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:	-



Page 17 of 17

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

16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classific	cation	Classification procedure		
-		-		
16.5.	Relevant H statements (number 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



Page 1 of 16

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	IXTURE AND OF THE COMPANY/UNDERTAKING	
1.1.	Product identifier				
	Trading name:	Trading name: PERIODIC		SOLUTION	
	Chemical name:	-	-		
	Catalogue number:	PK08-OT-	PK08-OT-X**		
1.2.	Relevant identified use	es of the sub	stance or mi	xture and uses advised against	
	Uses:		For use w	ith special staining kits.	
	Uses advised against:		Only the i	dentified uses are advised.	
	Reason why uses advis			uct is intended for use only as an <i>in vitro</i> diagnostic levice, 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 supplier	of the safet	y data sheet		
	Supplier:	ŀ	BioGnost Ltd		
	Address:	ı	Medjugorska 59, Zagreb +385 1 2409997 +385 1 2404039 msds@biognost.hr		
	Telephone number:	-			
	Fax no.:	-			
	e-mail of competent p	erson: <u>ı</u>			
	National contact:	-	-		
1.4.	Emergency telephone	number			
	National Protection an	National Protection and Rescue Dire Medical information: Other information:		112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2 HAZARDS INFORMATION				
2.1.	Classification of the substance or mixture				
2.1.1.	Classification (REGULATION (EC) N	No. 1272/2008 (CLP)		
	Hazard class and category	code:	Hazard statements*:		
	Not identified as hazardous substa	ance.	-		
2.1.2.	Additional information				
	-				
*For fu	ll text of Hazard- and EU Hazard-sta	tements: see Se	ection 16		
2.2.	Classification according to EC Dire	ective Nr. 1272/	2008 CLP)		
	Product identification:	PERIODIC ACI	D, 0.8 % SOLUTION		
	Identification number:	-			
	Authorization no.:	-			
	Hazard pictograms:	-			



Page 2 of 16

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 Properties:				
	No known endocrine disrupting p	properties			
	Results of PBT and vPvB assessment : According to the results of its assessment, this substance is not a PBT or a vPvB.				

SECTION 3 CO	SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS						
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)			
-	_	-	-	-			

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



Page 3 of 16

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

SECTIO	SECTION 6 ACCIDENTAL RELEASE MEASURES				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods: Evacuate members of all non-essential personnel and thos 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 containmer	nt and cleaning up			



Page 4 of 16

Trading name:	PERIODIC ACID, 0.8 % SOLUTION				
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 aw not smo	vay from sources of heat and ignition. Do ke.		
	Measures to prevent aerosol and dust generati	n: Secure p	proper ventilation.		
	Measures to protect the environment:	Prevent waterwa	spilling into the sewage system and sys.		
	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:	ventilated sto	ly closed and upright set containers in a well orage rooms, and away from sources of heat, other incompatible substances.		
	Packaging materials:	Manufacture	r'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 be resistant to chemicals. There must be no drain to directly leads into sewage system. Secure proper ventilation.			
	Further information on storage conditions:	and do not u	the unused material in the storage room se empty containers for storing other o not store with incompatible materials (see		
7.3.	Specific end use(s)				



Page 5 of 16

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

Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8 EX	(POSIII	RF CON	TROLS/PER	SONAL	PR∩T	FCTION				
		meters	TROES/TER	JOHAL	ı koı	LCTION				
Substance				upational exposure limit lues/short term values		Bio	ological limit values			
						ppm	n	ng/m³		3
-			-			-		-	No infor	mation available
Substance name:	—									
EC No:	_		CAS No:	_						
DNEL										
					Inc	lustrial				
Route of		A	Acute		Acut	e		Chron	ic	Chronic
exposure:		effe	ect local	effe	ct sys	temic		effect lo	ocal	effect systemic
Oral		-		-			-			-
Inhalation		-		-			-	-		-
Dermal		-		-			-			-
Critical physic	al parar	neters: s	solubility, fla	mmabilit	ty, cor	rosivity:		-		
		ı			Coi	nsumer	1			1
Route of			Acute		Acut			Chron		Chronic
exposure:		ette	ect local	effect systemic		effect local		ocal	effect systemic	
Oral		-		-			-			-
Inhalation		-		-			-			-
Dermal		-		-			-			-
PNEC	l	.4:				DNIEC				
Environmenta	protec	tion tar	get			PNEC				
Fresh water						No information available No information available				
Freshwater sediments										
Marine water					No information available					
Marine sediments Food chain					No information available					
Microorganisr	ns in so	wago tr	eatment			No information available No information available				
		waye II	catinent							
Soil (agricultural)				No information available						



Page 6 of 16

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

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 prexposure:	event	No information available					
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.					
	Technical measures to pr exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.					
8.2.2.	Personal protection equip	oment						
8.2.2.1.	Eye and face protection:	otection: Safety glasses that stick to face (preventing splashing) (EN 1 visor.						
8.2.2.2.	Skin protection							
	Hand protection:		ctive gloves must be according to the EU Directive 2016/425/EEC and ard EN 374. Glove material: nitrile rubber					
			Glove thickness: ≥0.50 mm Break through time: >480 min					
	Other skin protection:		or antistatic clothing made of natural fibers (such as cotton) with long eves (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 expe		See Section 6					
	Structural measures to pr exposure:	event	Use modern equipment.					
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.					
	Technical measures to pr exposure:	event	See Section 6					

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES



Page 7 of 16

Trading name:					
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
Lover and upper explosion limit:	No information available	No information available
Flash point:	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
pH:	No information available	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density:	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available

SECTIO	SECTION 10 STABILITY AND REACTIVITY									
10.1.	Reactivity:	See subsections 10.3 through 10.5.								
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.								
10.3.	Possibility of hazardous reactions:	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



Page 8 of 16

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

		1	:			:	
11.1. Informatio	n on hazard classes as	defined in Reg	ulation (EC) No 12	72/2008			
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure	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):				
	Specifi	c effects	Targe	t organ		Note	
Oral exposure:	No information a	available	No informati	on available	-		
Dermal exposure:	No information a	available	No informati	on available	-		
Inhalation exposure	e: No information a	available	No information available -				
	y irritation: nd corrosion	No info	rmation available				
11110000110	Exposure time	Species	Evaluation	Method		Note	
Skin irritation:	-	rabbit	-				
Eye irritation:	-	rabbit	-				
Sensitizatio	on						
Dermal exposure:	No information avail	able					
Inhalation exposure:	No information available	able					
Symptoms	related to the physica	l, chemical and	toxicological chara	acteristics			
Oral exposure:	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:			ure, resorption effe ingling sensation o		ely. Lon	g-term exposure	



Page 9 of 16

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

Inhalation exposi	ure:		of large amounts of vapors in inadequately ventilated perimeter may cause sneezing, headache and nausea.					
Eye exposure:		Direct eye co sensation.	contact may cause slight to moderate irritation, lacrimation and burning					
Repeate	ed dose	e toxicity (sub	acute, subchro	onic, chroni	ic)			
-		Dose	Exposure time	Species		Method	Evaluation	Note
Subacute oral	No availa	information able	No information available	No informati available		No information available	No information available	-
Subacute dermal	No availa	information able	No information available	No informati available	on	No information available	No information available	-
Subacute inhalation	No availa	information able	No information available	No informati available	on	No information available	No information available	-
Subchronic oral	No availa	information able	No information available	No informati available	on	No information available	No information available	-
Subchronic dermal	No availa	information able	No information available	No informati available	on	No information available	No information available	-
Subchronic inhalation	No availa	information able	No information available	No informati available	on	No information available	No information available	-
Chronic oral	No availa	information able	No information available	No informati available	on	No information available	No information available	-
Chronic dermal	No availa	information able	No information available	No informati available	on	No information available	No information available	-
Chronic inhalation	No availa	information able	No information available	No informati available		No information available	No information available	-
				· · · · · · · · · · · · · · · · · · ·	TOT			
Specific	target	1	y – repeated e pecific effects	exposure (S	101 F		an .	Note
Subacute oral			ation available		Target organ No information available			
Subacute dermal			ation available			nformation avai		
Subacute inhalat			ntion available					



Page 10 of 16

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

Subchro	onic oral	n available		No informatio	n availabl	e	_	
Subchro	onic dermal	No information	n available		No informatio	n availabl	e	_
Subchro	onic inhalation	No information	n available		No informatio	n availabl	e	-
Chronic	oral	No information	n available		No informatio	n availabl	e	-
Chronic	dermal	No information	n available		No informatio	n availabl	e	-
Chronic	inhalation	n available		No informatio	n availabl	e	-	
	CMR effects (c	carcinogenicity, m	utagenicity, r	reproduct	ive toxicity)			
	Carcinogenicit					not indica	ate carcin	ogenic effects.
	Mutagenicity i				s did not ind			
	Genotoxicity:	No informa				- 9		
	Mutagenicity i	in-vivo:	Current <i>in vivo</i> tests did not indicate mutagenic effects.					
	Germ cell mutagenicity: No information available							
	Reproductive toxicity: No toxicity on reproductive organs was determined in reproductive organs.						ed in reproductiv	
11.2		valuation of the (CMR propertion	es: -				
11.2.1.		upting properties						
	The substant contain command have endocring to Commission E 2017/2100 or	nce/mixture do ponents consid ne disrupting p REACH Article Delegated regula Commission Re 5 at levels of	es not ered to roperties 57(f) or tion (EU) egulation					
11.2.2.	Other informa	tions:						

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



Page 11 of 16

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

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. 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	-

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

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



Page 12 of 16

Tradin	g name:	PERIODIC ACID, 0.8 % SOLUTION										
Produc	ct code:	PK	08-OT-X*	·*	Date	e of co	mpilati	on: 2	21 Dec	2022	Versi	on: 4
-	N av	o info	ormation	-		No info	ormation le		inform ailable	ation	-	
	Biocon	centration	on factor (BCF)							1	
V	/alue		Speci	es	1	Method	k	E	valuatio	on		Note
No info	ormation le	No ava	in [.] ilable	formatio	n No info availab		on	No inf availal	formation ble	on	No inforr available	mation
	Chronic	c ecotox	icitv									
	Value		Dos	se E	xposure time	Spo	ecies	Met	hod	Eva	Evaluation	
Chronic	c toxicity	on fish	LC ₅₀	1	ormation ailable	No infori availa	mation able	No inform availal		No information available		-
	c toxicity ea (<i>Daph</i>		EC ₅₀	1	ormation ailable	No infori availa	mation able	No inform availal		No info	ormation ble	-
12.4.	Mobilit	ty in soil										
	1		icted distr	ibution ir	n environm	nental d	compart	ments:				
			available									
	Surface	e tensior	1:									
	Val	ue	°C		Concentra	ation		Meth	od		N	ote
	No informa availab	ation	No informatio available	าก	lo informa vailable	ition	No infavailat	ormatic ole	tion _			
	Adsorn	otion / de	esorption									
Transpo	-	A/D c	oefficient s constant		log Kow	Ev	/aporati	on rate		Method		Note
Soil-wa	ater N	0 vailable	informat		information		o inform	ation	No ir	nformati	on -	



Page 13 of 16

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

	t code.	0 01 X	Date 0.	compliation. 2	T Dec 2022	version. 4			
Water-a	ir No available	information	No information available	No information available	No information available	-			
Soil-air	No available	information	No information available	No information available	No information available	-			
12.5.	Results of PBT ar								
	according to REA	ACH Article 5	•	n Delegated regula	to have endocrine o	disrupting properties 0 or Commission			
12.6.	Endocrine disrup	oting properti	es						
	according to REA	ACH Article 5	•	n Delegated regula	to have endocrine o tion (EU) 2017/2100	disrupting properties O or Commission			
12.7.	Other adverse ef	ffects							
	No information available								
SECTIO	N 13 DISPOSAL (CONSIDERAT	TIONS						
13.1.	Waste treatme	ent methods							
13.1.1.	Product/Packa	ging disposa	:						
	Submit for disp Protection.	posal to the l	egal person autho	rized by the Minist	ry of Environmenta	l and Nature			
13.1.2.	Waste codes/v	waste designa	tions according to	Law:					
	No information		<u> </u>						
13.1.3.	Waste treatme	ent – relevant	information:						
	No information	n available							
13.1.4.	Sewage dispos	sal – relevant	information:						
			d of into the sewa	ge system.					
12.15	Oth I'	l	- .						
13.1.5.	Other disposal	recommend	ations:						



Trading name:

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

amended by Regulation (EU) No. 2020/878

Page 14 of 16 PERIODIC ACID, 0.8 % SOLUTION Date of compilation: 21 Dec 2022 Version: 4

Product code: PK08-OT-X**	Date of compilation: 21 Dec 2022 Version: 4
authorized by the minist	roduct's remains into the sewage system. Submit the remains to the collectors ry in charge. Do not dispose of the packaging into the sewage system. Submit
ignition may occur.	lectors authorized by the ministry in charge. Do not dispose of in places where
13.1.6. Relevant Community pro	ovisions:
-	
SECTION 14 TRANSPORT INFOR	MATION
Transporting/shipment by	road (ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by	rail (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	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:	-



Page 15 of 16

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

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

5.1. Safety, health and enviro	Safety, health and environmental regulations/legislation specific for the substance or mixture					
EU regulations						
Authorization and/or res	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);					



Page 16 of 16

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

	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 proute (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 us 1272/2008 (CLP)	sed to derive the classification for mixture according to Regulation (EC)		
Classifi	ication	Classification procedure		
-	-			
16.5.	Relevant H statements (number	er and full text)		
	H: -			
16.6.	Training advice:	-		
16.7.	Further information: t	** "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.		

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Exposure scenario resulting to Chemical safety assessment

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SAFETY DATA SHEET

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

Page 1 of 16

Trading name:	BIOSCHIFF REAGENT					
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

SECTI	ON 1: Identification of t	he substance	e/mixture	and of the company/undertaking		
1.1	Product identifier					
	Trading name:	BIOSCHIFF	REAGENT	JT		
	Chemical name:	-				
	Catalogue number:	BS-OT-X**	BS-OT-X**			
1.2	Relevant identified use	es of the subs	tance or n	nixture 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 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 Medical Devices and there is no reason to use it for other purpose.			
1.3	Details of the supplier	of the safety	data shee	t		
	Supplier:		BioGnost Ltd. Medjugorska 59, Zagreb			
	Address:					
	Telephone number:		+385 1 2	2409997		
	Telefax.:		+385 1 2	2404039		
	e-mail of competent p	erson:	msds@b	<u>piognost.hr</u>		
	National contact:		-			
1.4	Emergency telephone	number				
	National Protection an	d Rescue Dire	ectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	TION 2. Hazards identification						
2.1	Classification of the substan	Classification of the substance or mixture					
2.1.1	Classification according to F	Regulation (EC) No 1	1272/2008 (CLP)				
	Hazard class and ca	egory code:	Hazard statements*:				
	-		EUH031				
2.1.2.	Additional information						
	-						
*For fu	ıll text of Hazard- and EU Haza	rd-statements: see	SECTION 16				
2.2	Label elements						
	Product identification:	BIOSCHIFF REA	AGENT				
	Identification number: -						
	Authorization number:	Authorization number: -					
	Hazard pictograms:	-					



Page 2 of 16

Trading name:	BIOSCHIFF REAGENT					
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

	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 Prope	rties:				
	No known endocrine disrupting properties Results of PBT and vPvB assessment : According to the results of its assessment, this substitute of a vPvB.					

SECTION 3. Cor	SECTION 3. Composition/information on ingredients							
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)				
7681-57-4/ 231-673-0/ 016-063-00-2	-	1 – 3 %	sodium metabisulfite	Acute Tox. 4; H302 Eye Dam. 1; H318 EUH031				
7647-01-0/ 231-595-7/ 017-002-01-X	-	0.7 – 1 %	hydrochloric acid, 36.5%	Skin Corr. 1B; H314 Acute Tox. 3; H331				

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.
	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 effects, both acute and delayed	



Page 3 of 16

Trading name:		BIOSCHIFF REA	BIOSCHIFF REAGENT		
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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

SECTIO	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:	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 environment	ent with extinguishing media.			

SECTIO	SECTION 6. Accidental release measures				
6.1	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment:	Use personal protective equipment (see Section 8).			
	Accident prevention methods: Evacuate members of all non-essential personnel and those				
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:				
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).				
6.2	Environmental precautions:				
	Do not dispose of in sewage, dra Protection and Rescue Directora	ainage system and waterways. In case of large spillage contact National lite (NPRD) on 112.			



Page 4 of 16

Trading name:		BIOSCHIFF REA	BIOSCHIFF REAGENT		
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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 in	formation.			

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	on:	Secure proper ventilation.	
	Measures to protect the environment:	es to protect the environment:		
	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 incom	npatibilities		
	Technical measures and storage conditions:		htly closed and upright set containers in a atted storage rooms at temperatures ranging 25 °C.	
	Packaging materials:	Manufactu containers	ırer's original packaging. Avoid metal	
	Requirements for storage rooms and vessels:	equirements for storage rooms and vessels: Keep away from food and drink. Keet tightly closed.		
	Advices for storage equipment:	must be re	e must be made of hard material; floors esistant to chemicals. There must be no drain ly leads into sewage system. Secure proper in	



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

Page 5 of 16

Trading name:	BIOSCHIFF REAGENT				
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	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 Co	ntrol par		ols/perso							
i i	bstance					•	cupational exposure limit		Biological limit values	
0.000.000					ppm		mg/m³	J		
sodium metabisulfite 7681		7681-57	7-4		-/-		5/-	No information available		
Substance r	name:	_								
EC No:		_	CAS No	:	-					
DNEL										
						Industria	ıl			
Route of		Acı	ite		Acute			Chronic	Chronic	
exposure:		effect	local	ocal effect syste		emic		effect local	effect systemic	
Oral		-		-			-		-	
Inhalation		-		-			-		-	
Dermal		-		-			-		-	
Critical phys	sical para	meters: s	olubility,	flamm	ability, d	corrosivit	y:	-		
					(Consume	er		1	
Route of		Acı			Acute			Chronic	Chronic	
exposure:		effect	local	eft	ect syst	emic		effect local	effect systemic	
Oral		-		-			-		-	
Inhalation		-		-			-		-	
Dermal		-		-			-		-	
PNEC						1				
Environmental protection target			PNEC							
Fresh water					nation available					
Freshwater sediments				No in	No information available					
Marine wate						No in	No information available			
Marine sedi	ments					No in	No information available			



Food chain

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

No information available

Page 6 of 16

Trading name:		BIOSCHIFF REA	GENT		
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Microorga	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 controls			
	Substance/mixture related measure prevent exposure during identified		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.	
	Structural measures to prevent exposure:		In accordance with Section 7.	
	Organisational measures to prevent exposure: Technical measures to prevent exposure:		Organization of work in order to reduce other worker's influence during work process.	
			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:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.		
8.2.2.2.	Skin protection			
	Hand protection:	Protect	tive nitrile gloves, 0.11 mm thick (EN 374).	
	()ther skin protection:		ntistatic clothing made of natural fibers (such as cotton) ng sleeves (EN 340) and shoes that cover the entire foot.	
8.2.2.3.	Respiratory protection:	combir	e 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 controls			
	Substance/mixture related measures to prevent exposure:	See Se	ction 6	
	Structural measures to prevent exposure:	Vent Use modern equipment.		
Organisational measures to prevent exposure: Adapt the work process to the workplace.		the work process to the required working conditions of the ace.		
	Technical measures to prevent exposure:	See Se	ction 6	



Page 7 of 16

Trading name:		BIOSCHIFF REA	GENT		
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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
	Lover and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	рН:	<2	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	ON 10. Stability and reactivity	
10.1	Reactivity:	No information available
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.



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

Page 8 of 16

Trading name:		BIOSCHIFF REA	GENT		
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

11.1 Information	n on toxico	logical effects						
Acute toxic	ity:							
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}		Exposure time		Results	
Oral:	-	_		information lable	-		-	
Dermal:	-	_	1	information lable	-		-	
Inhalation:		-		information lable	-		-	
Specific tar	get organ	toxicity – single e	exposure (S	TOT SE):				
	Specific effects			Target or	gan		Note	
Oral:	Oral: No information available			No information available		_		
Dermal: No informa		nation available	tion available		No information available		-	
nhalation: No information available				No information available -				
Aspiration I	hazard:		No infor	mation available.				
Irritation ar	nd corrosio	n						
		posure time	Spec	ies Evaluatio	n Method		Note	
Skin corrosion/irritation:	-		-	-	-	- -		
Serious eye damage/irritation	-		-	-	-	-		
Sensitizatio	n							
Skin sensitization:		No information a	vailable					
Respiratory sensitiza	ation:	No information a	vailable					
Symptoms	related to	the physical che	mical and t	oxicological charac	teristics			
Oral exposure:	May ca	use gastrointesti	nal irritatio	n accompanied by	abdominal pa	ains and	cramps; high	
'		nt concentration	may induce	e vomiting and diar	rhea			



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

Page 9 of 16

Trading name:		BIOSCHIFF REA	GENT	_	
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Inhalation exposi	ure:	exposure and		y sensitive pers	high levels of co	•	rolonged as well as asthm
Eye exposure:		May cause ey	e irritation.				
Kepeate	ed dose	e toxicity (sub	acute, subchro	onic, chronic)			
		Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No availa	information able	No information available	No information available	No information available	No information available	-
Subacute dermal	No availa	information able	No information available	No information available	No information available	No information available	-
Subacute inhalation	No availa	information able	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 availa	information able	No information available	No information available	No information available	No information available	-
Chronic oral	No availa	information able	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 No information available		No information available	No information available	No information available	No information available	-	
C: C	to == 1	ongo to dell	., ", ", ", ", ", ", ", ", ", ", ", ", ",	vmosure (CTOT	DE).		
Specific	target	organ toxicit	<u> </u>	xposure (STOT		raan	Note
Subacute oral		No informa	Specific effection available	.13	Target o	-	
Subacute dermal			tion available		No information		
Subacute inhalat			tion available		No information		



Page 10 of 16

Trading name:		BIOSCHIFF REA	GENT		
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Subchronic oral	No information available		No information available	-			
Subchronic dermal	No information available		No information available	-			
Subchronic inhalatio	bchronic inhalation No information available		No information available	-			
Chronic oral	No information available		No information available	-			
Chronic dermal	No information available		No information available	-			
Chronic inhalation	No information available		No information available	-			
CMR effects	(carcinogenicity; mutagenicity; re	eproductive t	oxicity)				
Carcinogen	Carcinogenicity:		tion available				
Mutagenicit	Mutagenicity in vitro:		No information available				
Genotoxicit	/:	No information available					
Mutagenicit	y in vivo:	No informa	No information available				
Germ cell m	utagenicity:	No information available No information available					
Reproductiv	e toxicity:						
Summary properties:	properties: Information on other hazards:		the CMR No information available				
11.2 Information							
11.2.1. Endocrine d							
	endocrine disrupting properties uman health.						
11.2.2. Other inform	nations:						
_							

SECTION 12. Ecologic	cal informat	ion						
12.1 Toxicity	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	No information available	-		
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-		
Algae/aquatic plants	IC ₅₀	4 days	No information available	No information available	No information available	-		



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

Page 11 of 16

Trading name:		BIOSCHIFF REA	AGENT		
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Other of	organisms		-	-	-		-	-		-
Chronic (long-term) toxicity		m)	Dose	Exposur time	e	Species	Method	Eva	aluation	Note
Fish			LC ₅₀ 96 hours			o information ailable	No information available	No inforr availa	mation Ible	-
Crustacea:			EC ₅₀	48 hours		o information ailable	No information available	No inforr availa	mation Ible	-
Algae/aquatic plants		ints	IC ₅₀	72 hours		o information ailable	No information available	No inforr availa	mation Ible	-
Other organisms		-		-	-		-			
12.2	Persister	nce ar	nd degradal	oility						
	Abiotic o	degra	dation		:		,		:	
		De	gradation h	alf-lives		Method	Evaluati	on		Note
Marine	water	No in	formation a	available	No in availa	formation ble	No informati available	on	-	
Fresh water No informa		formation a	available	No in availa	formation Ible	No informati available	on	-		
Air No information available		available	No in availa	formation able	No informati available	on	-			
Soil No information available			No information vailable available		_					

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

12.3	Bioaccumulative potential						
	Octanol-water partition coefficient (log Kow)						
Value	e Concentration	рН	°C	Method	Evaluation	Note	
-	-	-	-	-	-	-	



Page 12 of 16

Trading na	ame:			BIO	SCHIF	HIFF REAGENT							
Product co	ode:	BS-O	T-X**		Date	of co	mpilati	on:	21 De	c 202	2	Version:	4
								3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4					
Bio	oconcent	ration	factor (BCF)										
Value			Species		M	lethod	l	E	/aluatio	on		Note	
No informa available	ation	No availa	inform ble	ation	No infor		n	No info		on	-		
Ch	nronic eco	otoxici	ty					,			·		
V	/alue		Dose		osure ime	Spe	ecies	Meth	nod	Eva	luation	N	ote
Chronic tox	kicity on f	fish	LC ₅₀	No infor availa	mation able	No inforr availa	mation Ible	No inform availab		No infor avail	mation able	-	
Chronic tox crustacea (-		EC ₅₀	No infor availa	mation able	No inforr availa	mation lble	No inform availab		No infor avail	mation able	-	
12.4 M	obility in	soil											
Kr	nown or p	oredict	ed distributi	on in e	environme	ental c	ompart	ments:					
	o informa		vailable										
Su	ırface ten	sion:											
	Value		°C	C	oncentrat	ion	0 0 0 0 0	Metho	od			Note	
	o formatior railable		o formation vailable		informat iilable	ion	No inf availal	ormatio ole	n 		_		
Ac	dsorption		•						***		-		
Transport	· ·		fficient constant	lc	og Kow	Eν	/aporati	on rate		Metho	d	No	te
Soil-water	No availa		nformation	No ir availa	nformatio able		o inform ailable	nation	No ir availa	nforma able	ation	-	
Water-air	No availa		nformation	No ir availa	nformatio able		o inform ailable	nation	No ir availa	nforma able	ation	-	



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

Page 13 of 16

Trading name:	BIOSCHIFF REAGENT						
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4		

Soil-air	No information available	No information available	No information available	No information available	-						
12.5.	Results of PBT and vPvB asse	ssment									
	Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB										
12.6.	Endocrine disrupting proper	ies									
	according to REACH Article 5	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 adverse effects										
	No information available										
SECTIO	N 13. Disposal consideration	าร									
13.1	Waste treatment methods										
13.1.1.	Product/Packaging dispose	al:									
	Submit for disposal to the Protection.	legal person autho	rized by the Minist	ry of Environmental	and Nature						
13.1.2.	Waste codes/waste design	ations according to	Law:								
	Packaging that contains re	sidual hazardous sı	ubstances or is con	taminated with haza	ardous substances						
13.1.3.	Waste treatment – relevan	t information:									
	No information available										
13.1.4.	Sewage disposal – relevant	information:									
	Waste must not be dispose		ge system.								
	•		<u> </u>								
13.1.5.	Other disposal recommend	lations:									
	Do not dispose of the proc authorized by the ministry the packaging to the collect	in charge. Do not o	dispose of the pack	aging into the sewa							
13.1.6.	Relevant Community provi	sions:									
	-										



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

Page 14 of 16

Trading name:	BIOSCHIFF REAGENT					
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

SECTION 14. Transport information	
Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (R	ID)
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 sea (II	MDG)
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 (IC	AO-TI/IATA-DGR)
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-



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

Page 15 of 16

Trading name:	BIOSCHIFF REAGENT						
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4		

Environmentally hazardous:		-
Special precautions for user:		-
Further information:	-	

SECTI 15.1	ON 15. Regulatory informa	
15.1	EU regulations	nmental regulations/legislation specific for the substance or mixture
	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	

SECTION 16. Other information			
16.1	Indication of changes:	-	



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

Page 16 of 16

Trading name:	BIOSCHIFF REAGENT					
Product code:	BS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4	

16.2	Abl	oreviations 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)			
Classif	icatio	า	Classification procedure			
_			-			
16.5.	Rel	evant H statements (numl	per and full text)			
	H:	H302	Harmful if swallowed.			
		H314	Causes severe skin burns and eye damage			
		H318	Causes serious eye damage.			
		H331	Toxic if inhaled.			
		(EUH031)	Contact with acids liberates toxic gas.			
16.6.	Tra	ining advice:	-			
			** "X" in the product code marks different volumes (different packagings of the product)			
16.7.			We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.			

ANNEX: Exposure scenario resulting to chemical safety assessment	
-	



Page 1 of 17

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

1.1.	Product identifier						
	Trading name:	HEMATO	HEMATOXYLIN ML				
	Chemical name:	-					
	Catalogue number:	HEMML	HEMML-OT-X**				
1.2.	Relevant identified use	es of the su	ubstance 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: Bi		BioGnost Ltd.	3ioGnost Ltd.			
	Address:		Medjugorska 59, Zagreb				
	Telephone number:		+385 1 2409997				
	Fax no.:		+385 1 2404039				
	e-mail of competent person:		msds@biognost.hr				
	National contact:	National contact:		-			
1.4.	Emergency telephone number						
	National Protection ar	nd Rescue	Directorate:	112			
	Medical information:			. 205 1 2240 242			
	Medical information:			+385 1 2348 342			

SECTIO	CTION 2. Hazards identification					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification according to Regul	Classification according to Regulation (EC) No 1272/2008 (CLP)				
	Hazard class and cate	Hazard class and category code: Hazard statements*:				
	Eye Irr. 2		H319			
2.1.2.	Additional information					
	-					
*For ful	I text of Hazard- and EU Hazard-sta	atements: see Section	16			
2.2.	Label elements	Label elements				
	Product identification:	HEMATOXYLIN ML				
	Identification number:	-				
	Authorization no.:	-				



Page 2 of 17

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 Properties:				
	No known endocrine disrupting properties Results of PBT and vPvB assessment : According to the results of its assessment, this substance is not a PBT or a vPvB.				

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		

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



Page 3 of 17

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	TION 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 proper protective equipment, including respiratory protection.				
5.4.	Additional information				
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.				

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



Page 4 of 17

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



Soil (agricultural)

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

Page 5 of 17

							1 4 9 5 5 1 1
Trading nam	ne:				НЕМА	TOXYLIN ML	
Product code	e:	HEMMI	L-OT-X**	F	Revision date:	27.03.2023.	Version: 9
				·			
Reco	ommer	ndations:			-		
Indu	strial s	sector spe	ecific solutio	ns:	-		
			_				
SECTION 8. E				al prote	ction		
8.1. Cont	trol pa	rameters					
Subs	tance		CAS I	No		al exposure limit ort term values	Biological limit values
3003	tarice		CAST	NO	ppm	mg/m³	Biological littlit values
_			-		-	-	No information available
			l		1	1	1
Substance name:	Alum	ninium su	Ilphate octa	decahyd	rate		
EC No:	233-	135-0	CAS No:	77	84-31-8		
DNEL							
					Industrial		
Route of		A	Acute		Acute	Chronic	Chronic
exposure:		effe	fect local e		ect systemic	effect local	effect systemic
Oral		-		-		-	-
Inhalation		-		-		-	13,4 mg/m ³
Dermal		-		-		-	3,8 mg/kg bw/day
Critical physic	al para	ameters:	solubility, fla	ammabil	ity, corrosivity:	-	
				l	Consumer	T	
Route of exposure:		1	Acute ect local	offe	Acute	Chronic effect local	Chronic offset systemic
Oral		ene	ect iocai	-	ect systemic	- effect local	effect systemic
Inhalation		-		_		_	
Dermal		_		_		_	
PNEC							
Environmental protection target					PNEC		
Fresh water					No info	rmation available	
Freshwater sediments					No info	rmation available	
Marine water					No info	rmation available	
Marine sedim	ents				No info	rmation available	
Food chain					No info	rmation available	
Microorganisms in sewage treatment					No info	rmation available	

No information available



Page 6 of 17

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

Air			No information available		
8.2.	Evnocuro controle				
8.2.1.	Exposure controls				
0.2.1.	Engineering measures Substance/mixture relate	-d			
	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 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 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				
	Hand protection:	Chem 374.	Glove material: nitrile rubber Glove thickness: > 0.11 mm Break through time: >480 min		
	Other skin protection:		r antistatic clothing made of natural fibers (such as cotton) with long res (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 in	nformation available		
8.2.3.	Environmental exposure	control	s		
	Substance/mixture relate measures to prevent exp		See Section 6		
	Structural measures to preserve:	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 prexposure:	event	See Section 6		

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



Page 7 of 17

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

	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
	Lover and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	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
.2.	Other information		

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

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



Page 8 of 17

	HEMAT	OXYLIN ML		
HEMML-OT-X**	Revision date:	27.03.2023.	Version:	9
	HEMML-OT-X**		HEMML-OT-X** Revision date: 27.03.2023.	

Product code:	HEMML-OT-X**	Revision date:	e: 27.03.2023.		Version: 9
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or	Exposui time	re Results
Oral exposure:	anhydrous (ECHA)	rabbit	ATE _{mixture}	-	>2.000-<5.000 mg/kg (aluminium sulphate octadecahydrate)
Dermal exposure:	anhydrous (ECHA)	rat	LD ₅₀	-	>5.000mg/kg (aluminium sulphate octadecahydrate)
Inhalation exposure:	No information available	-	LC ₅₀	-	-
Specific ta	rget organ toxicity – singl	•	1		
	Specific	effects	Target organ		Note
Oral exposure:	e: No information available		No information available		-
Dermal exposure:	No information avai	ilable	No inform available	nation	-
Inhalation exposure	e: No information avai	ilable	No inform available	nation	-
Respirator	y irritation:	No information av	ailable		
Irritation a	and corrosion				
l l	Exposure time	Species	Evaluati on	Meth od	Note
Skin irritation:	-	-	-	-	
Eye irritation:	_	-	-	- C	auses serious eye damage
Sensitizati					
Dermal exposure:	No information available				

Sensitizati	on					
Dermal exposure:	No information available					
Inhalation exposure: No information available						
Symptom	s related to the physical, chemical and toxicological characteristics					
Oral exposure:	No information available					
Dermal exposure:	No information available					



Page 9 of 17

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

Inhalation expos	ure:	No informati	on available					
Eye exposure:		Causes serio	us eye damage	9				
Repeat	ed dos	se toxicity (sub	oacute, subchr	onic, chronic)				
		Dose	Exposure time	Species	Method	Evaluation	า	Note
Subacute oral	No availa	information able	No information available	No information available	No information available	No inform	nation	-
Subacute dermal	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Subacute inhalation	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Subchronic oral	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Subchronic dermal	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Subchronic inhalation	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Chronic oral	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Chronic dermal	No availa	information able	No information available	No information available	No information available	No inform available	nation	-
Chronic inhalation			No information available	No information available	No information available	No inform available	nation	-
Specific	targe	t organ toxici	ty – repeated e	•	-			
			Specific effect	:S	Target or			Note
Subacute oral			tion available		No information		-	
Subacute derma			tion available		No information		-	
Subacute inhalat	tion		ition available		No information		-	
Subchronic oral		No informa	ition available		No information	available	_	



Page 10 of 17

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

Subchro	onic dermal No information avail		lable	No information available	-		
Subchro	onic inhalation No information availab		lable	No information available	-		
Chronic	oral	No information avai	lable	No information available	-		
Chronic	dermal	No information avai	lable	No information available	-		
Chronic	inhalation	No information avai	lable	No information available	-		
	CMR effects (carcinogenicity, mutag	enicity, reproduct	ive toxicity)			
	Carcinogenici	ty:	No information	available			
	Mutagenicity	in-vitro:	No information	available			
	Genotoxicity:		No information available				
	Mutagenicity	in-vivo:	No information available				
	Germ cell mut	agenicity:	No information available				
	Reproductive	toxicity:	No information available				
	Summary of e	valuation of the CMR	properties:	-			
11.2.	Information o	n other hazards:					
11.2.1.	Endocrine dis	rupting properties:					
	No known properties that	endocrine disrupt It affect human health.	•				
11.2.2.	Other informa	ations:					

SECTION	12. Ec	ologica	I inforn	nation
----------------	--------	---------	----------	--------

Toxicity 12.1.

Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Fish	ЕСНА	>85.9 mg/l (aluminium sulphate octadecahydrate)	-
Crustacea:	EC ₅₀	48 hours	aquatic invertebrates	ЕСНА	>200 mg/l (aluminium sulphate octadecahydrate)	-
Algae/aquatic plants	IC ₅₀	8 days	algae	No information available	-	-



Page 11 of 17

Trading name:	HEMATOXYLIN 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)	-

Persistence and degradability 12.2.

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				

Bioaccumulative potential 12.3.

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

Malua	Camaantustian	-11	۰,۲	Mathaad	F	NI-t-
Value	Concentration	рН	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-



Page 12 of 17

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

V	alue		Species		Meth	hod	Eva	luation		Not	:e
No information available		No information available		nation	No information available		No information available			No information available	
	Chronic	ecotox	icity								
	Value		Dose		osure me	Species	Meth	od	Ev	aluation	Note
Chronic	toxicity or	n fish	LC ₅₀	No inforr availa	nation i	No nformat on available	No inform available	ation	No info	ormation ble	-
	toxicity or ea (<i>Daphni</i>		EC ₅₀	No inforr availa	nation i	No nformat on available	No inform	ation	No info	ormation ble	_
		mation	icted distribut n available n:	ion in e	environme	ntal com	partments:				
	Value		°C		Concen	tration	Meth	od		Note	
	No informat available	ion	No inform available	nation	No inforr available		No inform available	ation	-		
	Adsorpti	on / de	esorption								
Transpo	ort	-	pefficient s constant	lo	g Kow	Evapo	ration rate	М	lethod	N	lote
Soil-wa	ter No avai	lable	information	No in availa	formation ble	No info	ormation le	No infa	ormatio ole	n -	
Water-a	air No avai	lable	information	No in availa	formation ble	No info	ormation le	No info	ormation ole	n -	
Soil-air	No	lable	information	No in availa	formation	No info	ormation	No inf	ormatio	n _	



Page 13 of 17

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

12.5.	Results of PBT and vPvB assessment
12.5.	No information available
	The information dvalidate
12.6.	Endocrine disrupting properties
	No known endocrine disrupting properties that affect the environment.
12.7.	Other adverse effects
12.7.	No adverse effects are expected.
	no auverse effects are expected.
SECTIO	N 13. Disposal considerations
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Western de de designations according to Laure
13.1.2.	Waste codes/waste designations according to Law: No information available
	NO IIIIOITTIALIOIT AVAIIADIE
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:
	-
CECT: C	
SECTIO	N 14. Transport information



Page 14 of 17

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

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by	rail (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 transpor	t (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	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	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:	-



Page 15 of 17

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.
ruftilei illioittiation.	The product is not subject to classification.

15.1.	Safety, health and enviro	nmental regulations/legislation specific for the substance or mixture
	EU regulations	
	Authorization and/or res	trictions of use
	Authorizations:	-
	Restrictions:	-
		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;
	Other EU regulations:	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-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessme	ent
	None	

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



Page 16 of 17

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

-		
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:		d -
16.4. Classification and procedure used t		e used to derive the classification for mixture according to Regulation (EC)
Classific	cation	Classification procedure
-		-
16.5.	Relevant H statements (num	nber and full text)
	H: 318	Causes serious eye damage.
	319	Causes serious eye irritation.
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exposure scenario resulting to Chemical safety assessment
-



Page 1 of 16

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

1.1.	Product identifier	the substant	e/mixture ai	nd of the company/undertaking	
1.1.		DI LUNIC DE	ACENIT		
	Trading name:	BLUING RE	AGENI		
	Chemical name:	-			
	Catalogue number:	BR-OT-X**	BR-OT-X**		
1.2.	Relevant identified us	es of the subs	es of the substance or mixture and uses advised against		
	Uses:		For conver	sion of red hematoxylin stained nuclei to blue.	
	Uses advised against:		Only the id	lentified uses are advised.	
	Reason why uses adv	Reason why uses advised against: The product is intended for use only as an <i>in vitro</i> d medical device, registered at the Agency for Medical Devices and there is no reason to use it for			
1.3.	Details of the supplie	r of the safety	data sheet		
	Supplier:	В	BioGnost Ltd.		
	Address:	N	Medjugorska 59, Zagreb		
	Telephone number:				
	Telephone number:	+	385 1 240999	97	
	Fax no.:		385 1 240999 385 1 240403		
	•	+		39	
	Fax no.:	+	385 1 240403	39	
1.4.	Fax no.: e-mail of competent	person: m	385 1 240403	39	
1.4.	Fax no.: e-mail of competent National contact:	person: m -	385 1 240403 nsds@biogno	39	
1.4.	Fax no.: e-mail of competent National contact: Emergency telephone	person: m -	385 1 240403 nsds@biogno	39 ost.hr	

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 categor	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 Section 16			
2.2.	Label elements				
	Product identification:	BLUING REAGENT			
	Identification number:	-			
	Authorization no.:	-			
	Hazard pictograms:	-			



No known endocrine disrupting properties.

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

Page 2 of 16

Trading name: Product code: BR-OT-X**		BLUING	REAGENT		
		Date of compilation:	23 January 2023	Version: 7	
	Signal wo	ord: ratements:	-		
	Precautionary statements:		-		
	Supplemetal hazard information (EU):		-		
2.3.	Other haz	zards			
	Endocrine	Disrupting Properties:			

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	-

SECTI	ON 4. First aid measures		
4.1.	Description of first aid measu	ıres	
	General notes:		-
	Following inhalation:		Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.
	Following skin contact:		Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact: Following ingestion:		Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.
			Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.
	Self-protection of the first aid	der:	Treat symptomatically.
4.2.	Most important symptoms a	nd effe	cts, both acute and delayed
	Following inhalation:	No in	formation available
	Following skin contact: No		formation available
	Following eye contact:	No in	formation available
	Following ingestion:	No in	oformation available
4.3.	Indication of any immediate	medica	al attention and special treatment needed



Page 3 of 16

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

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

SECTIO	SECTION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personne				
	Protective equipment:	Protective equipment: Use personal protective equipment (see Section 8).			
	Accident prevention methods: Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.				
	Emergency procedures: Mark the area using proper signs.				
6.1.2.	For emergency responders:				
	Wear protective equipment (see Section 8).				
6.2.	Environmental precautions:				
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.				
6.3.	Methods and material for containment and cleaning up				
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.			



Page 4 of 16

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

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 sectio	ns		
	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 not smoke.		
	Measures to prevent aerosol and dust generati	on: S	Secure proper ventilation.		
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.		
	Other measures:	-			
7.1.2.	Advice on general occupational hygiene:				
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.				
7.2.	Conditions for safe storage, including any incompatibilities				
	Technical measures and storage conditions:	ventil	in tightly closed and upright set containers in a well ated storage rooms, and away from sources of heat, jht, and other incompatible substances.		
	Packaging materials:	Manu	facturer's original packaging.		
	Requirements for storage rooms and vessels:		away from food and drink. Keep the containers y closed.		
	Advices for storage equipment:	be res	torage must be made of hard material; floors must sistant to chemicals. There must be no drain that ly leads into sewage system. Secure proper ation.		
	Further information on storage conditions:	and d	ot place the unused material in the storage room to not use empty containers for storing other icals. Do not store with incompatible materials (see on 9).		
7.3.	Specific end use(s)				



Microorganisms in sewage treatment

Soil (agricultural)

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

								Page 5 of 16
Trading name:					BLUING	G REAGENT		
Product code:	BR-OT-	X**	Date o	of con	npilation:	: 23 January	/ 2023	Version: 7
Do so marro	ndations							
Recomme		_:£:l±:			-			
industriai	sector spe	cific solution	15.		-			
SECTION 8. Expos	ure contr	ols/nersona	l protec	tion				
8.1. Control pa		013, per30110	ii protec					
				Occu	pational e	exposure limit		
Substance	!	CAS N	No			term values	Bio	logical limit values
				p	ppm	mg/m³		
-		-			-	-	No inforn	nation available
Substance -								
name:		CACNI						
EC No: -		CAS No:						
DNEL				Ind	ustrial			
		Acute		Acute		Chron	ic	Chronic
Route of exposure:		ect local	effect sy			effect lo		effect systemic
Oral	-		-			-		-
Inhalation	-		-			-		-
Dermal	-		-		-			-
Critical physical pa	rameters: s	solubility, fla	mmabilit	y, corr	osivity:	-		
				Con	sumer			
Route of exposure:	A	Acute		Acute	Chronic		ic	Chronic
Route of exposure.	effe	ect local	effe	ct syst	emic	effect local		effect systemic
Oral	-		-			-		-
Inhalation	-		-			-		-
Dermal			-			-		-
PNEC				T				
Environmental pro-	tection tar	get			PNEC			
Fresh water			No information available					
Freshwater sediments				No information available				
Marine water						mation availabl		
Marine sediments						mation availabl		
Food chain					No information available			

No information available

No information available



Page 6 of 16

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

Air			No information available			
8.2.	Exposure controls					
8.2.1.	Appropriate engineering controls					
	Substance/mixture relate measures to prevent expeduring identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to pr exposure:	event	No information available			
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equip	pment				
8.2.2.1.	2.2.1. Eye and face protection: Safety glasses that stick to face (preventing spivisor.					
8.2.2.2.	Skin protection					
			ective gloves must be according to the EU Directive 2016/425/EEC and lard EN 374.			
	Hand protection:		Glove material: nitrile rubber			
			Glove thickness: ≥0.50 mm Break through time: >480 min			
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) with long s (EN 13034), and shoes that cover the entire foot (EN 10335).			
8.2.2.3.	Respiratory protection:	filter fo	ctive full face mask (EN 136) or half mask (EN 140) equipped with a or organic vapors, type "A" (boiling point >65°C) acording to EN) used when concentration levels exceed GVI.			
8.2.2.4.	Thermal hazards:	No inf	ormation available			
8.2.3.	Environmental exposure	controls				
	Substance/mixture relate measures to prevent expe		See Section 6			
	Structural measures to prexposure:	event	Use modern equipment.			
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.			
	Technical measures to prexposure:	event	See Section 6			

SECTION 9. Physical and chemical properties



Page 7 of 16

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	
Lover and upper explosion limit:	No information available	No information available	
Flash point:	No information available	No information available	
Auto-ignition temperature:	No information available	No information available	
Decomposition temperature:	No information available	No information available	
pH:	>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



Page 8 of 16

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

			ulation (EC) No 127			
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	3 ,				
	Specif	ic effects	Target	organ		Note
Oral exposure:	No information	available	No informati	on available	-	
Dermal exposure:	No information	available	No information	No information available -		
Inhalation exposure	available	ole No information available -				
Aspiration	hazard:	No infor	mation available			
·						
Irritation a	nd corrosion:					
:	Exposure time	Species	Evaluation	Method		Note
Skin irritation:	-	-	-	-	-	
Eye irritation:	_	_	-	-	-	
		I				
Sensitization	on					
Dermal exposure:	No information avail	able				
Inhalation exposure:	No information avail	able				
· ·	1					
Symptoms	related to the physica	al, chemical and	toxicological chara	cteristics		
Oral exposure:	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. Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.					



Page 9 of 16

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

Inhalation expos	ure:		large amount eezing, heada	•		adequately vent	ilated perim	eter may cause
Eye exposure:		Direct eye co sensation.	ntact may cause slight to moderate irritation, lacrimation and burning					
Repeate	ed dos	e toxicity (sub	acute, subchro	onic, chron	ic)			
<u> </u>		Dose	Exposure time	Species	,	Method	Evaluation	n Note
Subacute oral	No avail	information able	No information available	No informat available		No information available	No informatio available	on -
Subacute dermal	No avail	information able	No information available	No informat available	-	No information available	No informatic available	n -
Subacute inhalation	No avail	information able	No information available	No informat available		No information available	No informatic available	on -
Subchronic oral	oral No information available		No information available	No informat available	-	No information available	No informatic available	on -
Subchronic dermal	No avail	information able	No information available	No informat available		No information available	No informatic available	on -
Subchronic inhalation	No avail	information able	No information available	No informat available		No information available	No informatio available	on -
Chronic oral	No avail	information able	No information available	No informat available		No information available	No informatic available	on -
Chronic dermal	No avail		No information available	No informat available		No information available	No informatic available	on -
Chronic inhalation			No information available	No informat available		No information available	No informatic available	on -
Cnocitic	taract	t organ tovicit	y – repeated e	vnocuro (C	TOT)E).		
Specific	target		pecific effects	Aposure (S	TOT R		an	Note
Subacute oral			ation available		No i	Target organ No information available		-
Subacute dermal			tion available			nformation avai		-
Subacute inhalat	ion	No informa	ition available		Noi	nformation avai	ilable	_



SECTION 12. Ecological information

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

Page 10 of 16

Trading name:			BLUING	REAGENT		
Product code: BR-OT-X**		Date of com	Date of compilation: 23 January 20		Version: 7	
C., b., b.,	NI. :f	nation available	NI :-	-ftiil-l-l-		
Subchronic oral				nformation available	-	
Subchronic dermal No information		nation available	No ii	nformation available	-	
Subchronic inhalation No information		nation available	No ir	nformation available	-	
Chronic oral No information as		nation available	No ir	nformation available	-	
Chronic dermal No information		nation available	No information available		-	
Chronic inhalation No informati		nation available	No ir	nformation available	-	
Carcinoge Mutageni	nicity: city <i>in-vitro</i> :		on test an	oxicity) nimals did not indicate ca d not indicate mutagen		
	,					
	city <i>in-vivo</i> :		vivo tests did not indicate mutagenic effects.			
Germ cell	mutagenicity:	No information				
Reproduc	tive toxicity:	No toxicity or organs.	reproduc	ctive organs was deter	mined in reproductive	
Summary	of evaluation of	the CMR properties:	-			

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 informations:
	-

12.1. Toxicity Exposure Acute toxicity Dose **Species** Method Evaluation Note time No information No information Fish LC_{50} 96 hours available available No information No information EC50 48 hours Crustacea:

Microorganisms LC ₅₀ 72 I	lavs	rmation No information	on	
3	avaii	lable available	_	-
Chronic (long-term) Ev	hours -	-	-	-
L Dose	rposure Spe	cies Method	Evaluation	Note



Page 11 of 16

Trading name:	BLUING REAGENT					
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7		
Product code:	BK-O1-X^^	Date of compliation:	23 January 2023	version: 7		

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. Persistence and degradability

Abiotic degradation

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

Biod	aar	าฝา	tion

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

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

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

ыосопсен	bioconcentration factor (bcr)							
Value	Species		Method	Evaluation	Note			



Page 12 of 16

	rading name: BLUING REAGENT											
Product code: BR-OT-X**			D	ate of co	ompilation:	23 Jar	nuary 2023	3	Vers	sion: 7		
No information No in available available			mation No inform			nation No info availab			No information available			
	Chronic	ecotoxici	ty									
	Value		Dose		osure ime	Species	Met	thod	Evalu	ıation	Note	
Chronic	toxicity o	n fish	LC ₅₀	No infori availa	mation able	No information available	No inform availab	ation i	No nforma availabl		-	
Chronic toxicity on crustacea (<i>Daphnia</i>)		EC ₅₀	No infori availa	mation able	No information available	No inform availab	ation i	No nforma vailabl		-		
12.4.	Mobility	in soil										
	Known o	r predict	ed distributi	on in e	environme	ental compai	tments:					
	No infor	mation a	vailable									
	Surface t	ension:					ension:					
	V / 1	alue °C										
	Value	9	°C	Co	oncentrat	ion	Metho	od		N	ote	
	No informat available	ion in		No	oncentrat informat iilable		formatio		-	N	ote	
	No informat	ion in	o formation	No	informat	ion No ir	formatio		-	N	ote	
	No informat	ion in	o formation vailable	No	informat	ion No ir	formatio		-	N	ote	
Transpo	No informat available Adsorpti	ion in	o formation vailable orption	No ava	informat	ion No ir	formation ble			N	ote	
	No informat available Adsorptiont	on / deso	o formation vailable orption	No ava	informat iilable og Kow	ion No ir availa	formation lble	n	hod			
Transpo Soil-wa ^s Water-a	No informat available Adsorptiont ter No ava	on / deso A/D coe Henry's c	o formation vailable orption orption onstant	No ava	informat iilable og Kow nformatio able	Evaporating No information available	formation ible ion rate mation	Met	hod mation			



Page 13 of 16

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

12.6.	Endocrine disrupting properti	ies				
12.0.	No known endocrine disrupting properties that affect the environment.					
	The known endeemie disrapa.	ng properties that aneet the environment.				
12.7.	Other adverse effects					
	No adverse effects are expec	ted.				
	N 13. Disposal consideration	<u>s</u>				
13.1.	Waste treatment methods					
13.1.1.	Product/Packaging disposa	l:				
	Submit for disposal to the le Protection.	egal person authorized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste designa	ations according to Law:				
	No information available	<u> </u>				
13.1.3.	Waste treatment – relevant	information:				
	No information available					
13.1.4.	Sewage disposal – relevant	information:				
	Waste must not be dispose	d of into the sewage system.				
13.1.5.	Other disposal recommend	ations:				
	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 provis	ions:				
	-					
SECTIO	N 14. Transport information					
	Transporting/shipment by roa	ad (ADR)				
UN num	ıber:	Not subject to transport regulations.				
UN prop	per shipping name:	-				
Transpo	rt hazard class(es):	-				



Page 14 of 16

Trading name:	BLUING REAGENT							
Product code:	BR-OT-X**	Date of compilation:	23 January 2023	Version: 7				
		······································						
Packing group:		-	-					
Environmentally ha	zardous:	-						
Special precautions	for user:	-						
Transportii	ng/shipment by rai	l (RID)						
UN number:		Not subject to transport	regulations.					
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	for user:	-						
Inland wat	erway transport (A	DN)						
UN number:		Not subject to transport	regulations.					
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-	-					
Special precautions	for user:	-						
Transportii	ng/shipment by sea	a (IMDG)						
UN number:		Not subject to transport regulations.						
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	for user:	-						
Transportii	ng/shipment by air	(ICAO-TI/IATA-DGR)						
UN number:		Not subject to transport	regulations.					
UN proper shipping	g name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally ha	zardous:	-						
Special precautions	for user:	-						
Further information	: The produc	t is not subject to classification	on.					



Page 15 of 16

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

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



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

Page 16 of 16

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

16.3.	Key literature references and source of data:		
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classific	cation	Classification procedure	
_		-	
16.5.	Relevant H statements (num	ber 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