

P.A.S. DIASTASE KIT

The kit contains:

Alpha-amylase, solution

Periodic acid, 0.8% solution

BioSchiff reagent

Hematoxylin ML


Bluing reagent

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

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	ALPHA-AMYLASE, SOLUTION
	Chemical name:	-
	Catalogue number:	ALF-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For differentiation between glycogen and P.A.S. -positive structures
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Warning statements*:
	Respiratory sensitisation. Category 1	H334
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	ALPHA-AMYLASE, SOLUTION
	Identification number:	-
	Authorisation number:	-

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.
Supplemental 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 %	α-Amylase	Resp. Sens. 1; H334

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.

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 first aider	-

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 in the labelling (see section 2.2) and/or in section 11	
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

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	
	-	

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.

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

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

SECTION 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. Thoroughly wash hands after work and before eating. Avoid skin contact.	
7.2.	Conditions for safe storage, including any incompatibilities	
	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.

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

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:		-
7.3.	Specific end use(s)	
	Recommendations:	Apart from the uses mentioned in section 1.2 no other specific uses are stipulated
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection				
8.1.	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m³	
	-	-	-	No information available
* Source - material safety data sheet provided by the raw materials supplier				
Substance:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:	Route of exposure:
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-
PNEC				
Environmental protection target		PNEC		
Fresh water		No information available		

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

Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

8.2.	Exposure controls
------	-------------------

8.2.1.	Appropriate engineering controls
--------	----------------------------------

	Substance/mixture related measures to prevent exposure during identified uses:	Do not eat, drink or smoke in the workspace. Use personal protective equipment. Wash hands after handling the product and before eating and/or drinking.
	Structural measures to prevent exposure:	Adequate ventilation should be provided so that exposure limits are not 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:	Safety glasses recommended. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
----------	--------------------------	---

8.2.2.2.	Skin protection
----------	-----------------

	Hand protection:	Protective gloves recommended. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.
	Other skin protection:	Wear lab 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 Section 6
--	---	---------------

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

SECTION 9. Physical and chemical properties			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	brown	No information available
	Odour/odour threshold:	typical/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	5.7 – 6.7	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	Water soluble	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	1.1 -1.2 g/ml	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
	-		

SECTION 10.: Stability and reactivity
--

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

SECTION 11. Toxicological information					
11.1.	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	No information available	-	-
Dermal:	No information available	rabbit	No information available	-	-
Inhalation:	No information available	rat	No information available	-	-
	Specific target organ toxicity - single exposure (STOT-SE):				
	Specific effects		Target organ	Note	
Oral:	No information available		No information available	-	
Dermal:	No information available		No information available	-	
Inhalation:	No information available		No information available	-	
	Aspiration hazard:		Insignificant danger at normal handling temperature.		
	Irritation and corrosion				
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	No information available	rabbit	Not irritating.	No information available	-
Serious eye damage/irritation	No information available	rabbit	Not irritating.	not specified	-
	Sensitization				

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

Skin sensitization:	No information available
Respiratory sensitization:	No information available

Symptoms related to the physical, chemical and toxicological characteristics	
--	--

Oral exposure:	No information available
Dermal exposure:	In case of prolonged or frequent skin contact irritation symptoms cannot be excluded
Inhalation exposure:	Repeated inhalation of enzyme dust caused by improper handling may cause allergic reactions including asthmatic bronchitis for sensitive persons
Eye exposure:	No information available

Repeated dose toxicity (subacute, subchronic, chronic)	
--	--

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

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

Specific target organ toxicity - repeated exposure (STOT-RE):			
	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-
CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)			
Carcinogenicity:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.		
Mutagenicity <i>in-vitro</i> :	No information available		
Genotoxicity:	No information available		
Mutagenicity <i>in-vivo</i> :	No information available		
Germ cell mutagenicity:	No information available		
Reproductive toxicity:	No information available		
Summary of evaluation of the CMR properties; :	No information available		
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:		
	To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.		

SECTION 12. Ecological information	
12.1.	Toxicity

Trade name:	ALPHA-AMYLASE, 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
Algae/aquatic plants:	IC ₅₀	72 hours	No information available	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	-

--	--	--	--	--

	Biodegradation
--	----------------

% Degradation	Time (days)	Method	Evaluation	Note
---------------	-------------	--------	------------	------

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

No information available	No information available	No information available	No information available	No information available

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
No information available	No information available	-	-	No information available	No information available	No information available

Bioconcentration Factor (BCF)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

Chronic ecotoxicity

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	Not expected.
Chronic toxicity on crustacea (Daphnia)	EC ₅₀	No information available	No information available	No information available	No information available	Not expected.

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:					
Surface tension:					
Value	°C	Concentration	Method	Note	

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

	No information available	No information available	No information available	No information available	-

Adsorption / desorption					
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-Water	No information available	No information available	No information available	No information available	-
Water-Air	No information available	No information available	No information available	No information available	-
Soil-Air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

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.

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself

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

13.1.2.	Waste codes/waste designations according to Law:
	-
13.1.3.	Waste codes/waste designations according to Law:
	Incinerating the product at high temperatures is recommended in order to avoid incomplete combustion products.
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	-
13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport information

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

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 (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 (ICAO-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:	
-	

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:
	-

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

Other EU regulations:	<p>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;</p> <p>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;</p> <p>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;</p> <p>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;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
National legislation:	<p>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</p>
15.2.	Chemical safety assessment
	None

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

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)		
Classification		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:		<p>** "X" in the product code marks different volumes (different packaging of the product)</p> <p>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.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment					
-					

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

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1.	Product identifier	
	Trading name:	PERIODIC ACID, 0.8 % SOLUTION
	Chemical name:	-
	Catalogue number:	PK08-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with special staining kits.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Fax no.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2 HAZARDS INFORMATION		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification (REGULATION (EC) No. 1272/2008 (CLP))	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Classification according to EC Directive Nr. 1272/2008 CLP)	
	Product identification:	PERIODIC ACID, 0.8 % SOLUTION
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	-

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 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)
-	-	-	-	-

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 aider:	Treat symptomatically.
4.2.	Most important symptoms and 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.

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	
	-	

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.	

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

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 involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	-	

SECTION 7 HANDLING AND STORAGE		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	

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 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	No information available

Substance name:	-
-----------------	---

EC No:	-	CAS No:	-
--------	---	---------	---

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity:	-
--	---

Consumer

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

PNEC

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

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 related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2. Personal protection equipment		
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:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥ 0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point $>65^{\circ}\text{C}$) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3. Environmental exposure controls		
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

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

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

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

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

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008					
Acute toxicity:					
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects		Target organ		Note
Oral exposure:	No information available		No information available		-
Dermal exposure:	No information available		No information available		-
Inhalation exposure:	No information available		No information available		-
Respiratory irritation:		No information available			
Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	rabbit	-	-	-
Eye irritation:	-	rabbit	-	-	-
Sensitization					
Dermal exposure:	No information available				
Inhalation exposure:	No information available				
Symptoms related to the physical, chemical and toxicological characteristics					
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:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.				

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

Inhalation exposure:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
Eye exposure:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.

Repeated dose toxicity (subacute, subchronic, chronic)
--

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

Specific target organ toxicity – repeated exposure (STOT RE):

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

Trading name:	PERIODIC ACID, 0.8 % SOLUTION				
Product code:	PK08-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 inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

	CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
	Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.
	Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.
	Genotoxicity:	No information available
	Mutagenicity <i>in-vivo</i> :	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.
	Summary of evaluation of the CMR properties:	-

11.2	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
11.2.2.	Other informations:
	-

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	-	-

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	-

Biodegradation

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

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log K_{ow}):

Value	Concentration	pH	°C	Method	Evaluation	Note
-------	---------------	----	----	--------	------------	------

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

-	No information available	-	-	No information available	No information available	-

	Bioconcentration factor (BCF)					
--	-------------------------------	--	--	--	--	--

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

	Chronic ecotoxicity					
--	---------------------	--	--	--	--	--

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

	Known or predicted distribution in environmental compartments:					
	No information available					

	Surface tension:					
--	------------------	--	--	--	--	--

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

	Adsorption / desorption					
--	-------------------------	--	--	--	--	--

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-

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

Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

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.

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

No information available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

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

13.1.2. Waste codes/waste designations according to Law:

No information available

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

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

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

13.1.6.	Relevant Community provisions:
	-

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
--	-------------------------------------

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

	Transporting/shipment by rail (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:	-

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

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:	-
Further information:	
-	

SECTION 15 REGULATORY INFORMATION	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations:
	-
	Restrictions:
	-
	Other EU regulations:
	<p>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;</p> <p>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;</p> <p>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;</p> <p>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;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)

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	

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

ANNEX:	
Exposure scenario resulting to Chemical safety assessment	
-	

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

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	BIOSCHIFF REAGENT
	Chemical name:	-
	Catalogue number:	BS-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For detecting aldehydes and mucous substances.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	-	EUH031
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	BIOSCHIFF REAGENT
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	-

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.
Supplemental hazard information (EU):	-

2.3	Other hazards
	<p>Endocrine Disrupting Properties: No known endocrine disrupting properties</p> <p>Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.</p>

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	

Trading name:	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 medical attention and special treatment needed	
	-	

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:	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 with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	

Trading name:	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 involved materials with water.
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C.
	Packaging materials:	Manufacturer's original packaging. Avoid metal containers.
	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.

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:	-

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
sodium metabisulfite	7681-57-4	-/-	5/-	No information available

Substance name:	-			
EC No:	-	CAS No:	-	

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

PNEC

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available

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

Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

8.2	Exposure controls
-----	-------------------

8.2.1.	Appropriate engineering controls
--------	----------------------------------

	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.

8.2.2.	Personal protection equipment
--------	-------------------------------

8.2.2.1.	Eye and face protection:	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:	Protective nitrile gloves, 0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Suitable mask (EN 136) or half mask (EN 140) equipped with a combined "A1 + Form" filter (EN 143) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available

8.2.3.	Environmental exposure controls
--------	---------------------------------

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

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

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour/odour threshold:	sharp/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	<2	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

SECTION 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.

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

SECTION 11. Toxicological information					
11.1	Information on toxicological effects				
	Acute toxicity:				
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	-	No information available	-	-
Dermal:	-	-	No information available	-	-
Inhalation:	-	-	No information available	-	-
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
	Aspiration hazard:		No information available.		
	Irritation and corrosion				
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-
	Sensitization				
Skin sensitization:		No information available			
Respiratory sensitization:		No information available			
	Symptoms related to the physical, chemical and toxicological characteristics				
Oral exposure:		May cause gastrointestinal irritation accompanied by abdominal pains and cramps; higher levels of concentration may induce vomiting and diarrhea.			
Dermal exposure:		May cause skin irritation.			

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

Inhalation exposure:	May cause respiratory system irritation. At high levels of concentration, prolonged exposure and when used by sensitive persons bronchospasm may occur, as well as asthma attack and gastrointestinal irritation.
Eye exposure:	May cause eye irritation.

Repeated dose toxicity (subacute, subchronic, chronic)
--

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

Specific target organ toxicity – repeated exposure (STOT RE):

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

Trading name:	BIOSCHIFF REAGENT				
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 inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)			
Carcinogenicity:	No information available		
Mutagenicity <i>in vitro</i> :	No information available		
Genotoxicity:	No information available		
Mutagenicity <i>in vivo</i> :	No information available		
Germ cell mutagenicity:	No information available		
Reproductive toxicity:	No information available		
Summary of evaluation of the CMR properties:	No information available		

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:	
	-	

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	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	-

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

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

12.2 Persistence and degradability

Abiotic degradation

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

Biodegradation

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

12.3 Bioaccumulative potential

Octanol-water partition coefficient (log K_{ow})

Value	Concentration	pH	°C	Method	Evaluation	Note
-	-	-	-	-	-	-

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

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4	Mobility in soil					
	Known or predicted distribution in environmental compartments:					
	No information available					
	Surface tension:					
	Value	°C	Concentration	Method	Note	
	No information available	No information available	No information available	No information available	-	

Adsorption / desorption						
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	No information available	-

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 assessment
-------	------------------------------------

	Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB
--	--

12.6.	Endocrine disrupting properties
-------	---------------------------------

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

12.7.	Other adverse effects
-------	-----------------------

	No information available
--	--------------------------

SECTION 13. Disposal considerations
--

13.1	Waste treatment methods
------	-------------------------

13.1.1.	Product/Packaging disposal:
---------	-----------------------------

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

13.1.2.	Waste codes/waste designations according to Law:
---------	--

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

13.1.3.	Waste treatment – relevant information:
---------	---

	No information available
--	--------------------------

13.1.4.	Sewage disposal – relevant information:
---------	---

	Waste must not be disposed of into the sewage system.
--	---

13.1.5.	Other disposal recommendations:
---------	---------------------------------

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

13.1.6.	Relevant Community provisions:
---------	--------------------------------

	-
--	---

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 (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:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
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:	-

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:	-

SECTION 15. Regulatory information		
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>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;</p> <p>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;</p> <p>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;</p> <p>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;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>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</p>
15.2	Chemical safety assessment	
	None	

SECTION 16. Other information		
16.1	Indication of changes:	-

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

16.2	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
Classification		Classification procedure
-		-
16.5.	Relevant H statements (number and full text)	
	H: H302 H314 H318 H331 (EUH031)	<p>Harmful if swallowed.</p> <p>Causes severe skin burns and eye damage</p> <p>Causes serious eye damage.</p> <p>Toxic if inhaled.</p> <p>Contact with acids liberates toxic gas.</p>
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>


ANNEX: Exposure scenario resulting to chemical safety assessment
-

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

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trading name:	HEMATOXYLIN ML
	Chemical name:	-
	Catalogue number:	HEMML-OT-X**
1.2.	Relevant identified uses of the substance or mixture 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 of the safety data sheet	
	Supplier:	BioGnost 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:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

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

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.
Supplemental 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

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

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	
	-	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, foam, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	No information available
5.3.	Advice for firefighters	
	Do not enter fire area without proper protective equipment, including respiratory protection.	
5.4.	Additional information	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

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 containment and cleaning up	

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

6.3.1.	Bundling, 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 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.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	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)	

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

Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	No information available

Substance name:	Aluminium sulphate octadecahydrate			
EC No:	233-135-0	CAS No:	7784-31-8	

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity:	-
--	---

Consumer

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

PNEC

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

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

Air		No information available
8.2.	Exposure controls	
8.2.1.	Engineering measures	
	Substance/mixture related measures to prevent exposure during identified uses:	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:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
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:	Chemical protection gloves are suitable, which are tested according to EN 374. Glove material: nitrile rubber Glove thickness: > 0.11 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	In case of inadequate ventilation wear respiratory protection.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace. Keep away from drains, surface and ground water.
	Technical measures to prevent exposure:	See Section 6

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

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

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

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

Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	anhydrous (ECHA)	rabbit	LD ₅₀	-	>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 target organ toxicity – single exposure (STOT SE):

	Specific effects	Target organ	Note
Oral exposure:	No information available	No information available	-
Dermal exposure:	No information available	No information available	-
Inhalation exposure:	No information available	No information available	-

Respiratory irritation: No information available

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	-	-	-	
Eye irritation:	-	-	-	-	Causes serious eye damage

Sensitization

Dermal exposure:	No information available
Inhalation exposure:	No information available

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	No information available
Dermal exposure:	No information available

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

Inhalation exposure:	No information available
Eye exposure:	Causes serious eye damage

Repeated dose toxicity (subacute, subchronic, chronic)
--

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

Specific target organ toxicity – repeated exposure (STOT RE):

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

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

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)			
Carcinogenicity:	No information available		
Mutagenicity <i>in-vitro</i> :	No information available		
Genotoxicity:	No information available		
Mutagenicity <i>in-vivo</i> :	No information available		
Germ cell mutagenicity:	No information available		
Reproductive toxicity:	No information available		

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:
	-

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

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)	-

12.2. Persistence and degradability

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

Biodegradation

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

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log Kow):						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

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

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil					
Known or predicted distribution in environmental compartments:					
No information available					
Surface tension:					
Value	°C	Concentration	Method	Note	
No information available	No information available	No information available	No information available	-	

Adsorption / desorption					
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-

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

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

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 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:	-
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:	-

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.
----------------------	---

SECTION 15. Regulatory information		
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>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;</p> <p>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;</p> <p>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;</p> <p>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;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>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</p>
15.2.	Chemical safety assessment	
	None	

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

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:		-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		
	H:	318 319	Causes serious eye damage. 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					
-					

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

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trading name:	BLUING REAGENT
	Chemical name:	-
	Catalogue number:	BR-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For conversion of red hematoxylin stained nuclei to blue.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Fax no.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	BLUING REAGENT
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	-

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

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

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

SECTION 4. First aid measures		
4.1.	Description of first aid measures	
	General notes:	-
	Following inhalation:	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 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:	No information available
	Following ingestion:	No information available
4.3.	Indication of any immediate medical attention and special treatment needed	

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

	-
--	---

SECTION 5. Firefighting measures					
5.1.	Extinguishing media				
	<table> <tr> <td>Suitable extinguishing media:</td><td>Small fire - water spray, dry powder, CO₂ Large fire - water spray or alcohol-resistant foam</td></tr> <tr> <td>Unsuitable extinguishing media:</td><td>water jet</td></tr> </table>	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam	Unsuitable extinguishing media:	water jet
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				
	<table> <tr> <td>Hazardous combustion products:</td><td>No information available</td></tr> </table>	Hazardous combustion products:	No information available		
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.				

SECTION 6. Accidental release measures							
6.1.	Personal precautions, protective equipment and emergency procedures						
6.1.1.	For non-emergency personnel						
	<table> <tr> <td>Protective equipment:</td><td>Use personal protective equipment (see Section 8).</td></tr> <tr> <td>Accident prevention methods:</td><td>Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.</td></tr> <tr> <td>Emergency procedures:</td><td>Mark the area using proper signs.</td></tr> </table>	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.
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.	<table> <tr> <td>Bunding, covering of drains; capping procedures:</td><td>Sand or clay barriers.</td></tr> </table>	Bunding, covering of drains; capping procedures:	Sand or clay barriers.				
Bunding, covering of drains; capping procedures:	Sand or clay barriers.						

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 involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	

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

Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	No information available

Substance name:	-
-----------------	---

EC No:	-	CAS No:	-
--------	---	---------	---

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity:	-
--	---

Consumer

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

PNEC

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

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 related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment	
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:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties

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

9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Color:	light blue	No information available
	Odour/odour threshold:	no information available/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	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
9.2.	Other information		
	-		

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
--

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

11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral exposure:	No information available		No information available		-
Dermal exposure:	No information available		No information available		-
Inhalation exposure:	No information available		No information available		-
	Aspiration hazard:		No information available		
	Irritation and corrosion:				
	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	-	-	-	-
Eye irritation:	-	-	-	-	-
	Sensitization				
Dermal exposure:	No information available				
Inhalation exposure:	No information available				
	Symptoms related to the physical, chemical and toxicological characteristics				
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:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.				

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

Inhalation exposure:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
Eye exposure:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.

Repeated dose toxicity (subacute, subchronic, chronic)
--

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

Specific target organ toxicity – repeated exposure (STOT RE):

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

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

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

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)
--

Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.
Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	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.

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:
---------	---------------------

-

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	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

Trading name:	BLUING REAGENT					
Product code:	BR-OT-X**	Date of compilation:	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	-

Biodegradation

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

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log K_{ow})

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

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
-------	---------	--------	------------	------

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

No information available	No information available	No information available	No information available	No information available

	Chronic ecotoxicity					
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

	Known or predicted distribution in environmental compartments:				
	No information available				
	Surface tension:				
	Value	°C	Concentration	Method	Note
	No information available	No information available	No information available	No information available	-

Adsorption / desorption

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

No information available

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

12.6.	Endocrine disrupting properties
	No known endocrine disrupting properties that affect the environment.
12.7.	Other adverse effects
	No adverse effects are expected.
SECTION 13. Disposal considerations	
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-
SECTION 14. Transport information	
	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-

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

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:	-
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:	-
Further information:	
The product is not subject to classification.	

SECTION 15. Regulatory information

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 restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>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;</p> <p>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;</p> <p>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;</p> <p>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;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment	
	None	

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

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)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H: -	-
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment
-