

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

Page 1 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

1.1.	Product identifier				
	Substance name:	WATER BLUE, C.I. 42755			
	EC No:	249-113-9			
	Synonyms:	Acid Blue	22		
	Catalogue number:	WB-P-X**			
	REACH registration number:	_			
	CAS No:	28631-66-	-5		
	Index no.:	-			
1.2.	Relevant identified uses of the	e substance	or mixture and uses advised against		
	Uses:		For staining of connective tissues using Mallory and Gomori trichrome methods.		
	Uses advised against:		Only the identified uses are advised.		
	Reason why uses advised aga	ainst:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device listed in the Registry of medical devices 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	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 person:		-		
1.4.	Emergency telephone number	er			
	National Protection and Resc Directorate:	ue	112		
	Medical information:		+385 1 2348 342		
	Other information:		-		

SECTIO	SECTION 2. Hazards identification					
2.1.	Classification of the substance or mixture					
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)					
	Hazard class and category code: Hazard statements*:					
	Skin Irrit. 2	H315				
	Eye Irrit. 2 H319					
	STOT SE 3	H335				



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

Page 2 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

2.1.2.	Additional information			
	-			
*For fu	ll text of Hazard- and EU Hazard-	statements: see Section 16		
2.2.	Label elements			
	Product identification:	WATER BLUE, C.I. 42755		
	Identification number:	-		
	Authorisation number:	-		
	Hazard pictograms:	GHS07		
	Signal word:	Warning		
	Hazard statements:	H315 Causes skin irritation.H319 Causes serious eye irritation.H335 May cause respiratory irritation.		
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/attention.		
	Further information:	-		
2.3.	Other hazards			
	Endocrine Disrupting Properties:			
	No known endocrine disruptin	g properties		
	Results of PBT and vPvB asserts PBT or a vPvB.	Results of PBT and vPvB assessment : According to the results of its assessment, this substance is not a PBT or a vPvB.		

SECTION 3. C	SECTION 3. Composition/information on ingredients						
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)			
28631-66-5	249-113-9	-	Disodium hydrogen aminomethyl[[4- [(sulphonatophenyl)amino]phen yl][4- [(sulphonatophenyl)imino]cycloh exa-2,5-dien-1-	100			



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

Page 3 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

			ylidene]methyl]benzenesulphona te		
SECTION	ON 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 begin rinsing with copious amounts of water for at least 15 min. Seek medical assistance if the symptoms of irritation remain.		
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide ope using clean fingers. If the symptoms remain, immediately ca a physician.			
	Following ingestion:		DO NOT induce vomiting. If the afflicted person is unconscious, do not provide them with anything orally. Drink at most two glasses of water. Seek medical assistance.		
	Self-protection of the first	aider	-		
4.2.	Most important symptoms	Most important symptoms and effects, both acute and delayed			
	Following inhalation:	Harmful if	inhaled.		
	After skin contact:	Harmful in	contact with skin.		
	Following eye contact: Risk of serio		ious damage to eyes.		
	Following ingestion:	Harmful if	swallowed.		
4.3.	Indication of any immedia	te medical atter	ntion and special treatment needed		
	-				

SECTIO	ECTION 5. Firefighting measures				
5.1.	Extinguishing media				
	Suitable extinguishing media:	Water, foam, dry powder, CO ₂			
	Unsuitable extinguishing media:	-			
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 com	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.			
	Cool closed containers exposed to fire	e with water spray or vapor.			
5.4.	Additional information				
	Make sure the water used for extinguishing fire does not contaminate water surface or underground waters system.				



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

Page 4 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

SECTIO	ON 6. Accidental relea	se measures		
6.1.	Personal precautions, protective equipment and emergency procedures			
6.1.1.	For non-emergency	personnel		
	Protective equipme	nt:	Use personal protective equipment (see Section 8).	
	Accident prevention	methods:	Avoid breathing in dust. Avoid touching the substance. Secure proper ventilation.	
	Emergency procedu	res:	Leave the hazardous area, take notice of the emergency procedures.	
6.1.2.	For emergency resp	onders:		
	-			
6.2.	Environmental preca	autions:		
	Do not allow the product enter drainage.			
6.3.	Methods and mater	ial for preventing	spreading and cleaning	
6.3.1.	For creating barriers, covering and sealing:	the possible m	Cover the drains. Collect, bind and pump out all the spilled material. Take notice of the possible material restriction (see Sections 7 and 10). Collect in dry form. Avoid generation of dust.	
6.3.2.	Cleaning up:	Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.		
6.3.3.	Other information:	-	-	
6.4.	Reference to other s	sections		
	Indications about waste treatment, see Section 13.			

SECTIO	ECTION 7. Handling and storage				
7.1.	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use sparkling tools.			
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.			
	Environmental precautions:	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 incompa	tibilities			



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

Page 5 of 17

Trading name:		WATER BLUE, C.I. 42755			
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

	Technical measures and storage conditions:	Minimize dust formation. Avoid breathing in dust. Avoid contact with skin, eyes, and clothes. Keep in tightly closed containers.
	Containers materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep in a tightly closed container. Keep in cool, dry and well ventilated space away from non-compatible substances.
	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:	No information available.
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

8.1. Co	ntrol parameters				
<u> </u>	ostance	CAS No		nal exposure limit hort term values	Biological limit values
			ppm	mg/m³	
-		-	-	-	-
Does not cor	ntain substances r	egulated by the	professional expo	sure limit values.	
Substance name:	-				
EC No:	-	CAS No:	-		
DNEL	·				
			Industrial		
Route of		Acute	Acute	Chronic	Chronic
exposure:	eff	ect local	effect syste	mic effect loca	l effect systemic
Oral	-		-	-	-
Inhalation	-		-	-	-
Dermal	-		-	-	-
Critical physi	cal parameters: sc	lubility, flammal	bility, corrosivity:		·
			Consumer		
Route of		Acute	Acute	Chronic	Chronic
exposure:	eff	ect local	effect syste	mic effect loca	l effect systemic
Oral	-		-	-	-
Inhalation	-		-	-	-



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

Page 6 of 17

Trading name:		WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3	

Dermal	-	-	-	-
PNEC				
Environn	nental protection target	PNEC		
Fresh wa	ter	No information available		
Freshwat	er sediments	No information available		
Marine v	vater	No information available		
Marine s	ediments	No information	available	
Food cha	Food chain		available	
Microorg	Microorganisms in sewage treatment		available	
Soil (agri	cultural)	No information	available	
Air		No information	available	
8.2.	Exposure controls			
8.2.1.	Appropriate engineering controls		Ţ	
	Substance/mixture related measures to put during identified uses:	to prevent exposure Use personal protective equiperate, drink or smoke in the wo		
	Structural measures to prevent exposure		No information available	
	Organisational measures to prevent expo	osure:	Organization of work in order to reduce other worker's influence during work process.	
	Technical measures for preventing exposure:		Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.	
8.2.2.	Personal protection equipment		:	
8.2.2.1.	Eye and face protection:	Safety glasses th (EN 166).	nat stick to face (prev	venting splashing) or visor
8.2.2.2.	Skin protection			
	Hand protection:	specifications of standard EN374 full contact: Glo		rubber
		splash contact:	oves material: Nitrile	
		Glo	ove thickness: 0.11 m	nm



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

Page 7 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

		Break through time:> 480 min
	Other skin protection:	In normal circumstances use cotton clothes and adequate footwear, such as rubber boots or shoes that cover the entire foot. In case of spillage risk use clothes made of impermeable material suitable for protection against liquid chemicals (Viton, PVC himex - HRN EN 465) and footwear made of the same material.
8.2.2.3.	Respiratory protection:	Required when dust are generated. Recommended filter type: Filter P 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances.
8.2.2.4.	Thermal hazards:	-
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 for preventing exposure:	See Section 6

9.1.	Information on basic physical and chemic	al properties	
		Value	Method
	Physical state:	powder	No information available
	Colour:	Purple-dark red-brown	No information available
	Odour/odour threshold:	odourless/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lover and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	рН:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available



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

Page 8 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
.2.	Other information		
	-		

SECTIO	SECTION 10. Stability and reactivity			
10.1.	Reactivity:	No information available		
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).		
10.3.	Possibility of hazardous reactions:	Strong oxidizing agents		
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. 1	Γοxicological informati	on				
	mation on toxicological e					
Acut	e toxicity:					
Route of exposure:	Method	S	pecies	Dose LD ₅₀ /LC ₅₀	Exposure period	Result
Oral exposure:	No information available	No informa	No information available		-	_
Skin contact:	No information available	No information available		No information available	-	-
Inhaling:	No information available	No informa	tion available	No information available	-	-
_				•		
Spec	ific target organ toxicity	– single expo	sure (STOT SE):			
	Specific effects		Target organ		Note	
Oral exposure:	No information availab	le	No information	n available	-	
Skin contact:	No information availab	le	No information	n available	_	



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

Page 9 of 17

Trading name:	WATER BLUE, C.I. 42755					
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3	

Inhaling:	No information	n available	No information	n available	-	
Aspira	ation hazard:	No i	nformation avai	lable		
		:				
Irritati	ion and corrosi	on				
		Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritat	tion: No info	ormation available	No information available	-	No information available	No information available
Serious eye damage/irritatio	on No info	ormation available	No information available	-	No information available	No information available
Sensit	tization					
Skin contact:	No inform	nation available				
Inhaling:	No inform	nation available				
	,					
Symp	toms related to	the physical, chemica	al and toxicologi	cal characteristics	5	
Oral exposure:	No inform	nation available				
Skin contact:	No inform	nation available				
Inhaling:	No inform	nation available				
Eye contact:	No inform	nation available				
Repea	ated dose toxici	ty (subacute, subchro	nic, chronic)			,
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	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	-	-
inhaling intermation		No information available	No information available	No information available	-	-
Subchronic oral No information available		No information available	No information available	No information available	-	-
Subchronic dermal	No information	No information available	No information	No information	-	-



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

Page 10 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

toxicity	available	available		available			
Subchronic inhalation	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	_		-
Chronic dermal toxicity	No information available	No information available	intormation		_		-
Chronic inhalation	No information available	No information available	No information available	No information available	-		-
			(57.57.5)				
Spec	cific target organ	toxicity – repeated ex					
		Specific 6	effects	Target organ		Note	
Subacute oral		No information available		No information available	_		
Subacute dermal		No information available		No information available	-		
Subacute inhaling toxicity		No information available		No information available	_		
Subchronic or	al	No information available		No information available	_		
Subchronic de	ermal toxicity	No information available		No information available	-		
Subchronic inhalation		No information available		No information available	_		
Chronic oral		No information available		No information available	_		
Chronic dermal toxicity		No information available		No information available	_		
Chronic inhalation		No information available		No information	-		



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

Page 11 of 17

Trading name:	WATER BLUE, C.I. 42755					
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3	

		available
	CMR effects (carcinogenicity, mutagenicity	r, reproductive toxicity)
Carcino	genicity:	No information available
Mutage	nicity in-vitro:	No information available
Genotox	kicity:	No information available
Mutage	nicity <i>in-vivo</i> :	No information available
Germ ce	ell mutagenicity:	No information available
Reprodu	uctive toxicity:	No information available
	Summary of evaluation of the CMR properties:	No information available
	<u> </u>	
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 (short-term) toxicity	Dose	Exposure period	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	-	-			



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

Page 12 of 17

Trading name:	WATER BLUE, C.I. 42755						
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3		

Microorganisms	-	_	-	_	–	-
Chronic (long-term) toxicity	Dose	Exposure period	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	-	_
Microorganisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

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

Biodegradation

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

12.3. Bioaccumulative potential

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

	, , ,							
Value	Concentratio n	рН	°C	Method	Evaluation	Note		
No information available	No information available	-	-	No information available	No information available	No information available		



BIOGNOST & SAFETY DATA STILL! According to Regulation (EC) No. 1907/2006 amended by Regulation (EU) No. 2020/878

											Page 1	3 of 17	
Trading	g name	e:					WATER BL	JE, C.I.	. 42755				
Produc	t code	: V	VB-P-X*	*		Re	vision date:	21 De	21 Dec 2022		Version:		3
		:					·				1		
	Bioco	ncentra	tion fact	or (BCF)									
Vá	alue		Sp	ecies			Method	Е	Evaluation		N	lote	
No infor			o inform vailable	ation		No in availa	formation ble	No in	formation ble		No informa vailable	ntion	
										8 8 9 9 9 9 9 9 9			
	Chror	nic ecot	oxicity	1	1		1			1			
	Val	ue		Dose	Expo: peri		Species		Method	Eva	aluation	No	te
Chronic toxicity on fish			LC ₅₀	No inform on availa		No information available	-				-		
Chronic toxicity on crustacea (Daphnia)		EC ₅₀	No informati on available		No information available	-		_		-			
12.4.	Mobi	lity in so	oil										
	Know	n or pre	edicted c	listributi	on in e	nviror	nmental compa	rtments	S:				
	No in	formati	on availa	ble									
	Surfa	ce tensi	on:										
	Vá	alue		°C		Concentratio	n l	Method		No	te		
No information No info		formation available		No information available		ormation ailable	-						
	Adso	rption /	desorpt	ion	1		1						
Transport			O coeffici iry's cons		log k	Kow	Evaporation rate		Method		No	te	
Soil-Water		No info	ormatior ble	constant			No information available		ormation ailable	-			



SAFETY DATA SHEET

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

Page 14 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

Water-air		No information available	No informati on available	No information available	No information available	-	
Soil-air		No information available	No informati on available	No information available	No information available	-	
12.5.	Results	of PBT and vPvB as	ssessment				
	No info	ormation available					
12.6.	Endocr	ine disrupting prop	erties				
	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 a	Other adverse effects					
	No information available						

6565101	140 50 1 11 11
SECTION	N 13. Disposal considerations
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature
	Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.



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

Page 15 of 17

Trading name:	WATER BLUE, C.I. 42755			-	
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

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 hazard(s):	-			
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 hazard(s):	-			
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:	-			
Environmental hazard(s):	-			
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 hazard(s):	-			
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/IA	ΓA-DGR)			
UN number:	Not subject to transport regulations.			



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

Page 16 of 17

Trading name:	WATER BLUE, C.I. 42755			-	
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Further 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:	-				
		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;				
	Other EU regulations:	Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;				
	_	Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;				
		Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;				
		REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);				
	Information accordin guideline)	g 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-				
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Transport of Hazardous Substances Act				
15.2.	Chemical safety asses	sment				

SECTION 16. Other information



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

Page 17 of 17

Trading name:	WATER BLUE, C.I. 42755				
Product code:	WB-P-X**	Revision date:	21 Dec 2022	Version:	3

16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
16.4.	Relevant H statements (number and full tex	xt)
	315 H: 319 335	Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.
16.5.	Training advice:	-
16.6.	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.

Α	N	N	EX	:
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Exposure scenario resulting to Chemical safety assessment