

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

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Trading name:		WRIGHT'S STAIN				
Product code:	WS-P-X**	Revision date:	06.08.2019.	Version:	2	

SECTI	ON 1. Identification of the sub	stance	e/mixture a	nd of the company/undertaking	
1.1.	Product identifier				
	Substance name:	WRIC	SHT'S STAIN		
	Chemical name:	-			
	Catalogue number:	WS-F	P-X**		
1.2.	Relevant identified uses of the substance or mixture and uses advised against				
	Uses:		For micros	сору.	
	Uses advised against:	Only the identified uses are advised. The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.			
	Reason why uses advised aga				
1.3.	Details of the supplier of the safety data sheet				
	Supplier:	Bi	oGnost Ltd.		
	Address:	М	edjugorska	59, Zagreb	
	Telephone number:	+	385 1 24099	97	
	Fax no.:	+	385 1 24040	39	
	e-mail of competent person:	<u>m</u>	sds@biogno	ost.hr	
	National contact:	-			
1.4.	Emergency telephone numbe	r			
	National Protection and Rescu	ue Dire	ectorate:	112	
	Medical information:			+385 1 2348 342	
	Other information:			-	

SECTIO	SECTION 2. Hazards information						
2.1.	Classification of the substance or m	Classification of the substance or mixture					
2.1.1.	Classification according to Regulation	on (EC) No 127.	2/2008 (CLP)				
	Hazard class and category	code:	Hazard statements*:				
	Acute Tox. 4		H302				
	Eye Irrit. 2		H319				
2.1.2.	Additional information						
	-						
*For ful	l text of Hazard- and EU Hazard-state	ements: see Sec	tion 16				
2.2.	Label elements						
	Product identification:	WRIGHT'S STA	AIN				
	Identification number:	-					
	Authorization no.:	-					



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	Hazard pictograms:	GHS07
	Signal word:	Warning
	Hazard statements:	H302 Harmful if swallowed. H319 Causes serious eye irritation
	Precautionary statements:	P261 Avoid breathing dust/fume/gas/mist/vapors/spray. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P301+P312+P330 IF SWALLOWED: Call Poison Center or doctor. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
	Supplemetal hazard information (EU):	-
2.3.	Other hazards	
	-	

SECTION 3. Co	SECTION 3. Composition/information on ingredients						
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Name	Classification according to Regulation (EC) No 1272/2008 (CLP)			
61-73-4/ 200-515-2/ -	-	60 – 100 %	Methylthionium chloride	Acute Tox. 4; H302			
17372-87-1/ 241-409-6/ -	-	30 – 60 %	Disodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)benzoate	Eye Irrit. 2; H319			

SECTION	ECTION 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. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-			



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		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 without consulting physician. If the afflicted person is unconscious, do not place anything in their mouth.		
	Self-protection of the first aider:	-		
4.2.	Most important symptoms and effects, both acute and delayed			
	Following inhalation:	Allergic persons may display irritation after prolonged or repeated exposure.		
	Following skin contact:	Allergic persons may display irritation.		
	Following eye contact:	May cause irritation.		
	Following ingestion:	Swallowing may cause discomfort in abdomen and abdominal pains.		
4.3.	Indication of any immediate medi	cal attention and special treatment needed		
	-			

SECTIO	ION 5. Firefighting measures					
5.1.	Extinguishing media					
	Suitable extinguishing media:	In case of fire use water spray to cool fire expose containers. Use water, dry chemical, chemical foam, or alcohol-resistant foam, or appropriate foam. Use agent most appropriate to extinguish fire.				
	Unsuitable extinguishing media:	No information available				
5.2.	Special hazards arising from the substance or mixture					
	Hazardous combustion products:	Carbon, nitrogen, sulfur, sodium oxides.				
5.3.	Advice for firefighters					
	As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH approved or equivalent, and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Dust can be an explosion hazard when exposed to heat or flame.					
5.4.	Additional information					
	Remove sources of heat and igniti	on. Do not contaminate the environment with extinguishing media.				

SECTIO	SECTION 6. Accidental release measures				
6.1.	Personal precautions, protective eq	uipment and emergency procedures			
6.1.1.	For non-emergency personnel				
	Protective equipment: Use personal protective equipment (see Section 8)				
	Accident prevention methods:	Avoid inhaling dust. Avoid contact with the substance. Secure proper ventilation.			
	Emergency procedures:	Mark the area using proper signs.			



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6.1.2.	For emergency responders:		
	Use protective equipm (see Section 8).	nent; in case of inadequate ventilation use adequate airways protective equipment	
6.2.	Environmental precau	tions:	
	Do not dispose of in s	ewage, drainage system or waterways.	
6.3.	Methods and material for containment and cleaning up		
6.3.1.	For creating barriers, covering and sealing:	Cap the drains. Collect, bundle and pump out everything that got spilled. Pay attention to the possible material restrictions (see Sections 7 and 10). Collect in dry form.	
6.3.2.	Cleaning up: Vacuum or sweep, then store in a tightly closed container. Prevent formation of dust. Ventilate the room		
6.3.3.	Other information: -		
6.4.	Reference to other sections		
	For indications of was	te processing see Section 13.	

SECTIO	ON 7. Handling and storage		
7.1.	Precautions for safe handling		
7.1.1.	Protection measures		
	Measures to prevent fire:		-
	Measures to prevent aerosol and dust generation	n:	Secure proper ventilation.
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.
	Other measures:		-
7.1.2.	Advice on general occupational hygiene:		
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.		
7.2.	Conditions for safe storage, including any incom	npatibilitie	S
	Technical measures and storage conditions:	mist o	ize dust formation. Avoid inhaling vapor, dust, r gas. Avoid contact with skin, eyes and clothes. n tightly closed container. Avoid swallowing and ing.
	Packaging materials:	Manuf	acturer's original packaging.
	Requirements for storage rooms and vessels:	•	container tightly closed. Keep in cool, dry and entilated space, away from incompatible nces.
	Advices for storage equipment:	must b drain t	orage must be made of hard material; floors be resistant to chemicals. There must be no hat directly leads into sewage system. Secure r ventilation.
	Further information on storage conditions:	No info	ormation available.
7.3.	Specific end use(s)		



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	Recomm	endations:		-			
	Industria	l sector specific sol	utions:	-			
SECTI	ON 8. Expo	sure controls/pers	onal protec	tion			
8.1.	Control p	parameters					
	Substar	ice	CAS No	limit value	es/short term	Biologica	ıl limit values

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

ppm

mg/m³

DNEL

	Industrial					
Route of	Acute	Acute	Chronic	Chronic		
exposure:	effect local	effect systemic	effect local	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
Air	No information available



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8.2.	Exposure controls			
8.2.1.	Appropriate engineering co	ontrols		
	Substance/mixture related of prevent exposure during ide			Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prev	ent expo	osure:	No information available
	Organisational measures to	prevent	t exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prev	ent expo	osure:	Use with appropriate ventilation.
8.2.2.	Personal protection equipm	nent		
8.2.2.1.	Eye and face protection:	Safety	glasses that	stick to face (preventing splashing) or visor.
8.2.2.2.	Skin protection			
	Hand protection:	materials: - polychloroprene, - nitrile rubber, 0.3 - butyl rubber, 0.5 - polyvinyl chloride		5 mm, mm,
	Other skin protection:			thing made of natural fibers (such as cotton) with long that cover the entire foot.
8.2.2.3.	Respiratory protection:			ing long-term exposure wear a protective mask or a d with filter A.
8.2.2.4.	Thermal hazards:	-		
8.2.3.	Environmental exposure co	ntrols		
	Substance/mixture related measures to prevent expose	ure: Se	ee Section 6	
	Structural measures to prevexposure:	prevent Use modern		quipment.
	Organisational measures to prevent exposure:		dapt the wor orkplace.	k process to the required working conditions of the
	Technical measures to prevexposure:	ent Se	ee Section 6	

SECTI	SECTION 9. Physical and chemical properties				
9.1.	. Information on basic physical and chemical properties				
		Value	Method		
	Physical state:	Solid (crystals)	No information available		
	Color:	Dark brown - green	No information available		
	Odor:	No information available	No information available		



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	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point;	210-211°C	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapor pressure:	No information available	No information available
	Vapor density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	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:	No information available					
10.4.	Conditions to avoid:	Heat, open flames, dusting.					
10.5.	Incompatible materials:	Strongly oxidizing media.					
10.6.	Hazardous decomposition products:	Carbon dioxides, nitrous oxides, sulfur oxides, hydrogen chloride.					

	SECTION 11	. Toxicological	information
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Information on toxicological effects 11.1.



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Acute toxi	city:							
Route of exposure:	Method	$\begin{array}{c} \text{D} \\ \text{Species} \end{array}$				Exposur	e time	Results
Oral exposure:	No information available	intorn				No info	rmation	-
Dermal exposure:	No information available	Intorn				No info	rmation	-
Inhalation exposure:	No information available	intorn				No info	rmation	-
Specific ta	rget organ toxicity -	- sinale exi	nosure (ST)	OT SF)·				
Jpceme to		ecific effec		J _ j.	Targ	et organ		Note
Oral exposure:	•	information available					_	
Dermal exposure:	No information av	information available				information - lable		
Inhalation exposure:	No information av	o information available				nformation le	-	
Aspiration	hazard:	N	lo informat	ion avai	lable			
Irritation a	and corrosion							
į	Exposure 1	time	Species	5	Evaluatio	on M	ethod	Note
Skin corrosion/irritation		rmation	No informatio available	n -		No infor availa	mation able	No information available
Serious eye damage/irritation	erious eye No information No information			n -	n - intormation		No information available	
						,		
Sensitizati		. , .						
	Dermal exposure: No information available							
Inhalation exposure	e: No information	on availabl	е					
Symptoms	related to the phys	ical, chem	ical and to	xicologi	cal chara	octeristics		
Oral exposure:	Swallowing m	nay cause o	discomfort	in abdo	men and	d abdomina	l pains.	
Dermal exposure:	Allergic perso	ns may di	splay irritat	tion.				



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Inhalation expo	sure:	-		lay irr	itation afte	r prolonged or r	epea	ted exposu	re.
Eye exposure:		May cause irritation.							
Donos	tad dasa	tovicity (cub		nia al	ronis)				
кереа	tea aose	toxicity (sur	pacute, subchro	nic, cr	ronic)				
	[Oose	Exposure time	Spe	ecies	Method	Eva	luation	Note
Subacute oral	No ir availab	nformation le	No information available		ormation ilable	No information available		ormation ilable	-
Subacute dermal	No ir availab	nformation le	No information available		ormation ilable	No information available		ormation ilable	-
Subacute inhalation	No ir availab	nformation le	No information available		ormation ilable	No information available		ormation ilable	-
Subchronic oral	No ir availab	nformation le	No information available		ormation ilable	No information available		ormation ilable	-
Subchronic dermal	No ir availab	nformation le	No information available		ormation ilable	No information available		ormation ilable	-
Subchronic inhalation	No ir availab	nformation le			ormation ilable	No information available		ormation ilable	-
Chronic oral	No ir availab	nformation le	No information available		ormation ilable	No information available		ormation ilable	-
Chronic dermal	No ir availab	nformation le	No information available		ormation ilable	No information available		ormation ilable	-
Chronic inhalation	No ir availab	nformation le	No information available		ormation ilable	No information available		ormation ilable	-
					(6707.5				
Specifi	c target		ty – repeated ex	kposu					Nata
Cultural		•	ecific effects			rget organ			Note
Subacute oral Subacute derm			ation available ation available			ation available		-	
Subacute derma			ation available			nation available		_	
Subacute innaia			ation available			nation available		_	
Subchronic der			ation available			ation available		_	
Subchronic inha			ation available			ation available		_	



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Chroni	ic oral	No information availab	le	No information available	-		
Chroni	c dermal	dermal No information available		No information available	-		
Chroni	inhalation No information available		No information available	-			
	CMR effects	(carcinogenicity, mutageni	city re	enroductive toxicity)			
Carcino				tion available			
Mutag	enicity in-vitro:	No in	ıforma	tion available			
Genote	oxicity:	No in	ıforma	tion available			
Mutag			forma	tion available			
Germ cell mutagenicity: No info		o information available					
Reprod	ductive toxicity:	No in	information available				
	····•						
	Summary of evaluation of the CMR properties:			lo information available			
11.2.	Practical experiences:						
	Remarks relevant for classification:			No information available			
	Other remarks:		No information available				
11.3.	General note	S:					
	-						

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	72 hours	No information available	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	No	No	-



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			information available	information available	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

				ī
	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	-

Bioaccumulative potential 12.3.

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

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

Bioconce	ntration	factor	(RCF)
DIOCOLICE	าเนสนอก	iactor	IDCEL

Value	Species	Method	Evaluation	Note
No information available				



Other adverse effects

No information available

12.6.

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	Chronic ecot	oxicity	****				
	Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic t	toxicity on fis	n LC ₅₀	information	No information available	No informatio available	No n information available	n -
Chronic toxicity on crustacea (Daphnia)		information	No information available	No informatio available	No n information available	n -	
12.4.	Mobility in so	pil					
	Known or predicted distribution in environmental compartments:						
	No informati	on available					
	Surface tensi	on:					
	Value	°C	Concentrati	on N	Method		Note
	No information available	No information available	No information	on No info availab	ormation lle	-	
	^ d 1	desorption					
	Adsorption /	description	IOU KOW		Method		
Transpor	t A/D	coefficient y's constant	log Kow	Evapora rate		Method	Note
<u> </u>	t A/D Henr	coefficient y's constant information	log Kow No information available	rate	mation No		Note -
Transpor	t A/D Henr No availabl	coefficient y's constant information e	No information	n No informavailable	mation No ava	information	Note -



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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.
1212	Wests and a function as a second in the Laure
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 INFORM	MATION
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:	-
Transporting/shipment by	inland waterways (ADN)
UN number:	Not subject to transport regulations.



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UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by sea (IM	MDG)
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 (ICA	AO-TI/IATA-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Further information: -	

SECTION 15. Regulatory information			
. Safety, he	Safety, health and environmental regulations/legislation specific for the substance or mixture		
EU regula	ulations		
Authoriza	rization and/or restric	tions of use	
Authoriza	rizations:	-	
Restrictio	tions:	-	
Other EU	EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/200 of the European Parliament and Council from	
Other EU	EU regulations:	and amendments to the Regulation (EC) No. 1907/2006 of the E Parliament and Council on registration, evaluation, authorization restriction of chemical substances (REACH);	



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		17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives		
	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, Transport of Hazardous Substances Act		
15.2.	Chemical safety assessment			
	None			

SECTIO	SECTION 16. Other information				
16.1.	Indi	cation of changes:	-		
16.2.			PBT	Stable, bioaccumulative and toxic	
			vPvB Strongly stable and strongly bioaccumulative.		
	Abb	Abbreviations and acronyms:	LD ₅₀	Lethal dose, 50%	
			LC ₅₀	Lethal concentration, 50%	
			STOT-SE	Specific target organ toxicity - single exposure	
16.3.	Key literature references and source of data:		-		
16.4.	Rele	Relevant H statements (number and full text)			
	H:	302	Harmful if swallowed.		
	н.	319	Causes serious	s eye irritation.	
16.5.	Training advice:		-		
			** "X" in the product code marks different volumes (different packaging of the product)		
16.6.	Furt	her information:	We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

ANNEX:

EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT