

EOSIN AND NIGROSINE VITAL KIT

The kit contains:

Eosin Y, isotonic solution Nigrosine, isotonic solution



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Trade name:	EOSIN Y, ISOTONIC SOLUTION						
Product code:	EIO-OT-X**	Date of compilation:	14 November 2022	Version:	4		

1.1.	Product identifier	e substai	nce/m	iixture and	d of the company/undertaking	
1.1.					7.00	
		OSIN Y, I	ISOTO	NIC SOLU	TION	
	Chemical name: -					
	Product code: E	IO-OT-X	**			
1.2.	Relevant identified uses	Relevant identified uses of the substance or mixture and uses advised against				
	Uses:			Aqueous s kit.	solution of Eosin Y used with Eosin and nigrosin vital	
	Uses advised against:			Only the id	dentified uses are advised.	
	Reason why uses advised against		The product is intended for use only as an <i>in vitro</i> diagnostic medical device and there is no reason to use it for other purposes.			
1.3.	Details of the supplier of	Details of the supplier of the safety data sheet				
	Supplier:	[BioGn	inost Ltd.		
	Address:	I	Medju	ugorska 59, Zagreb		
	Telephone number:	-	+385 ^	35 1 2409997		
	Telefax:	-	+385 ′	85 1 2404039		
	e-mail of competent pe	erson:	msds@	s@biognost.hr		
	National contact:		_			
1.4.	Emergency telephone r	numbers				
	National Protection and	d Rescue	Direct	torate:	112	
	Medical information:				+385 1 2348 342	
	Other information:				-	

SECTIO	CTION 2. Hazards identification					
2.1.	Classification of the substan	Classification of the substance or mixture				
2.1.1.	Classification according to R	egulation (EC) No 1	272/2008 (CLP)			
	Hazard class and cate	egory code:	Hazard statement*:			
	Skin. Sens. 1 H317					
2.1.2.	Additional information					
	-					
*For the	full text of H and EUH phrase	s see Section 16.				
2.2.	Label elements					
	Product identification: EOSIN Y, ISOTONIC SOLUTION					
	Identification number:	-				
	Authorisation number:	-				



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	Hazard pictograms:	GHS07		
	Signal word:	Warning		
	Hazard statement:	H317 May cause an allergic skin reaction.		
	Precautionary statement:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P308 + P313 IF exposed or concerned: Get medical advice/attention.		
	Supplemetal hazard information (EU):	-		
2.3.	Other hazards			
	No known endocrine disrupting properties. 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. Co	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)				
17372-87-1/ 241-409-6/ -	-	3 – 5 %	disodium 2-(2,4,5,7- tetrabromo-6-oxide-3- oxoxanthen-9-yl) benzoate	Skin. Sens. 1; H317				

SECTIO	SECTION 4. First aid measures					
4.1.	Description of first aid measures					
	General notes:	Move out of dangerous area. Show this safety data sheet to the doctor and first responders.				
	Following inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Get medical advice.				
	Following skin contact:	Wash off with soap and plenty of water. If irritation occurs and persists: Get medical advice.				
	Following eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation occurs and persists: Get medical advice.				
	Following ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water.				



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	Self-protection of the first aider	-
4.2.	Most important symptom	s and effects, both acute and delayed
	Following inhalation:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
4.3.	Indication of any immedia	te medical attention and special treatment needed
	Treat symptomatically.	

SECTIO	CTION 5. Firefighting measures					
5.1.	Extinguishing media					
	Suitable extinguishing media:	Use dry chemical, CO ₂ , water spray (FOG) or foam.				
	Unsuitable extinguishing media:	Avoid solid water stream as it may scatter and spread fire.				
5.2.	Special hazards arising from the su	bstance or mixture				
	Hazardous by products of fire:	Use water spray to cool fire exposed container surfaces and to protect personnel. Thermal decomposition can produce carbon monoxide (highly toxic) and carbon dioxide (an asphyxiant at sufficient concentrations).				
5.3.	Advice for firefighters					
	Use a self-contained open-circuit containers exposed to fire with war	ompressed air breathing apparatus and fireproof clothing. Cool closed ter spray or vapor.				
5.4.	Additional information					
	3 ,	ring due to increase in pressure. Remove sources of heat and nvironment with extinguishing media.				

SECTIO	SECTION 6. Accidental release measures				
6.1.	Personal precautions, protective equipment and emergency procedures				
6.1.1.	For non-emergency personnel				
	Protective equipment: Use suitable personal protective equipment (see Section 8).				
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.			
	Emergency procedures:	Mark the area using proper signs.			
6.1.2.	For emergency responders:				
	Use protective equipment; in case (see Section 8).	e of inadequate ventilation use adequate airways protective equipment			



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6.2.	Environmental precautions:	Environmental precautions:					
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.						
6.3.	Methods and materials for co	ontainment and cleaning up					
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.					
6.3.2.	Cleaning up:	After removing the product, use water to wash the work space and used materials.					
6.3.3.	Other information:	No information available.					
6.4.	Reference to other sections						
	-						

SECTIO	DN 7. Handling and storage					
7.1.	Precautions for safe handling					
7.1. 7.1.1. 7.1.2.	Protection measures					
	Measures to prevent fire:		Use in well ventilated storage rooms. Refer to the manufacturer's recommendations.			
	Measures to prevent aerosol and dust generation	on:	Secure proper ventilation.			
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.			
	Other measures:	e. Thoroughly wash hands after work and before eating				
7.1.2.	Advice on general occupational hygiene:					
	o not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.					
	Conditions for safe storage, including any incompatibilities					
	Technical measures and storage conditions:	tightly closed and upright set containers in a tilated storage rooms at temperatures from 15 to 25 °C.				
	Packaging materials:	Manufact	turer's original packaging.			
	Requirements for storage rooms and vessels:	Keep awa	ay from food and drink. Keep the containers osed.			
	Advices for storage equipment:	must be i	ge must be made of hard material; floors resistant to chemicals. There must be no t directly leads into sewage system. Secure entilation.			
	Further information on storage conditions:	Do not place the unused mate				
7.3.	Specific end use(s)					



Soil (agricultural)

Air

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

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	endations	s: pecific soluti	ons:	-				
SECTION 8. EXPO	SURE CO	NTROLS / F	PERSONAL F	PROTECTIO	N			
8.1. Control	paramete	´S						
Substance	.	CAS I		•	exposure limit term values	Biolog	ical limit values	
				ppm	mg/m³			
-		-		-	-		-	
Substance: -			1					
EC No: -		CAS No:	-					
DNEL								
			1	Industrial				
Route of exposure	:	te effect Acute eff local system			Chronic effect local		Chronic effect systemic	
Oral	-		-		-			
Inhalation	-		-		-	-		
Dermal	-		-		-	-		
Critical physical pa	rameters:	solubility, fl	ammability,	corrosivity:	-			
				Consumer				
Route of exposure	•	te effect local		effect emic	Chronic effect local		Chronic effect systemic	
Oral	-		-		-	-		
Inhalation	-		-		-	-		
Dermal	-		-		-	-		
PNEC						<u>.</u>		
Environmental protection target			PNEC					
Fresh water				No infor	No information available			
Freshwater sediments				No infor	mation available	e		
Marine water				No infor	No information available			
Marine sediments				No infor	No information available			
Food chain				No infor	mation available	e		
Microorganisms in	sewage t	reatment		No infor	No information available			

No information available

No information available



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8.2.	Exposure controls					
8.2.1.	Appropriate engineering controls					
	Substance/mixture related measure to prevent exposure during identifuses:	I lise nersonal protective equipment. Do not eat, drink or				
	Structural measures to prevent exposure:	No information available				
	Organisational measures to prever 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.	EVA and tace protection.					
8.2.2.1.	Eye and face protection:	Safety glasses tested and approved under appropriate standards such as EN 166(EU).				
8.2.2.2.	Skin protection:					
	Hand protection:	Handle with chemical resistant gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.				
	Other skin protection:	No specific protective equipment required.				
8.2.2.3.	Respiratory protection:	Use when overexposure potential. Improper use of respirators is dangerous.				
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	SECTION 9. Physical and chemical properties							
9.1.	Information on basic p	Information on basic physical and chemical properties						
		Value	Method					
	Physical state:	liquid	No information available					
	Colour:	red	No information available					



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.2.	Other information		
	Particle characteristics:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Vapour pressure:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Solubility:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	pH:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Flash point:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flammability:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Odour/odour threshold:	No information available	No information available

SECTIO	SECTION 10.: Stability and reactivity						
10.1.	Reactivity:	Not reactive under normal conditions.					
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:	Contact with incompatible materials and temperature extremes.					
10.5.	Incompatible materials:	Strong oxidizers.					
10.6.	Hazardous decomposition products:	Does not decompose under normal conditions. During fire, thermal decomposition can produce carbon monoxide (highly toxic) and carbon dioxide (as asphyxiant as sufficient concentrations).					

SECTION 11. Toxicological information



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11.1. Infor	mation on t	oxicological e	ffects						
Acut	e toxicity:								
Route of exposure:		Method	Species		Effective Dose LD_{50}/LC_{50} or $ATE_{mixture}$		Exposure time		Results
Oral:		nformation vailable	-		No inform availa	ation -			-
Dermal:		nformation vailable		-	No inform availa	ation	-		-
Inhalation:		nformation vailable		-	No inform availa	ation	-		-
Sned	cific target o	rgan toxicity -	sinale e	exposure (ST	OT-SF)				
Spec	and target o		ecific effe	•	J_/.	Targ	et organ		Note
Oral:	<u>'</u>					-		-	
Dermal:		ormation ava				-	-		
Inhalation:		ormation avai				_	-		
	i								
Aspi	iration hazar	d:		-	-				
Irrita	ation and co	rrosion							
		Exposure	time	Specie	S	Evaluati	ion N	1ethod	Note
Skin corrosion	/irritation:	No info	rmation	rabbit	-		-		mild skin irritation
Serious irritati	on to eyes:	No info	rmation	_	-		-		-
Sens	sitization								
Skin sensitizat		o information	available	e.					
Respiratory sensitization:		o information							
		1		1 1 1					
		ed to physical,			ological p	propertie	es		
Oral exposure		No known s							
Dermal exposi	ure:	No known sp	pecific sy	mptoms. M	ay cause	skin irrit	tation.		



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Inhalation expo	sure: N	No known specific symptoms.								
Eye exposure: No ki		lo kno	known specific symptoms.							
Repea	ated dose tox	cicity (subacute, subcl	hronic, chror	nic)					
	Dose		Exposure time	Species	S	Method	Evaluation	1	Note	
Subacute oral	No informa	ation	No information available	No informatic available	on	No information available	No informatic available	n	No information available	
Subacute dermal	No informa	ation	No information available	No informatio available	n	No information available	No informatio available	n	No information available	
Subacute inhalation	No informa	ation	No information available	No informatio available	on	No information available	No informatio available	n	No information available	
Subchronic oral	No informa	ation	No No information available available		No information available	No informatio available	n	No information available		
Subchronic dermal	No information available		No information available	No information available		No information available	No informatio available	n	No information available	
Subchronic inhalation	No informa	ation	No information available	No informatio available	on	No information available	No informatio available	n	No information available	
Chronic oral	No informa	ation	No information available	No informatio available	on	No information available	No informatio available	n	No information available	
Chronic dermal	No informa available	ation	No information available	No informatic available	on	No information available	No informatic available	n	No information available	
Chronic inhalation	No information available		No information available	No informatic available	on	No information available	No informatic available	on	No information available	
ï										
Speci	fic target org	an to	xicity - repeated	d exposure (S	STOT	-RE):				
			Specific ef	fects		Target org	an		Note	
Subacute oral		N	lo information available		No	No information available			information lable	
Subacute derma	al	N	o information available		No	No information available			information lable	



Subacute inhalation

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available

No information

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No information available

No information available

					avanable		
Subchro	onic oral	No information availa	able	No information available	No information available		
Subchronic dermal No information availa		able	No information available	No information available			
Subchro	onic inhalation	No information availa	able	No information available	No information available		
Chronic	oral	No information availa	able	No information available	No information available		
Chronic	dermal	No information availa	able	No information available	No information available		
Chronic inhalation No information avail		No information availa	able	No information available	No information available		
	CMR effects (carcino	genicity, mutagenicity,	reprodu	uctive toxicity)			
	Carcinogenicity:		Based on available data, the classification criteria are not met.				
	Mutagenicity in-vitro:		Based on available data, the classification criteria are not met.				
	Genotoxicity:		Based on available data, the classification criteria are not met.				
	Mutagenicity in-vivo		Based on available data, the classification criteria are not met.				
	Germ cell mutagenio	city:	Based on available data, the classification criteria are not met.				
	Reproductive toxicity	y:	Based on available data, the classification criteria are not met.				
	Summary of evaluation of the CMR properties:			ormation available			
11.2.	Information on othe	r hazards:					
11.2.1.	Endocrine disrupting	properties:					
	No known endocrine disrupting properties that affect human health.						
	1.2.2. Other information:						
11.2.2.	Other information.						

SECTIO	N 12. Ecological information
12.1.	Toxicity



Value

information

available

No

Concentration

No information

available

°C

рΗ

Method

No information

available

Evaluation

No information

available

Note

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Acute (short- toxicity	-term)	Dose	Exposur time	e Species	N	lethod	Evaluation	Note
Fish		LC ₅₀	96 hours	-	-		-	-
Crustacea:	EC ₅₀ 48 hours		-	-		-	-	
Algae/aquati	c plants:	IC ₅₀	72 hours	-	-		-	-
Other organi	sms	-	-	-	-		-	-
Chronic (long toxicity	g-term)	Doza	Exposur time	e Species	N	lethod	Evaluation	Note
Fish		LC ₅₀	96 hours	-	-		-	-
Crustacea:		EC ₅₀	48 hours	-	-		-	-
Algae/aquati	c plants:	IC ₅₀	72 hours	-	-		-	-
Other organi	sms	-	-	-	-		-	-
	iotic deg		· ·	Method			Evaluation	Note
Marine		Degradation half-lives information available		Method No information available		No inf	Evaluation ormation	Note -
water	No info	ormation av	silabla	No information available		availab	ormation	
Fresh water	INO IIIIC	orriation av	allable	INO IIIIOITTIALIOIT AVAIIADIE		availab		-
Air	No info	ormation ava	ailable	No information available		No info	ormation ole	-
Soil	No info	ormation ava	ailable	No information available		No info	ormation	-
						avallat	ле	
Bio	degrada	ition						
% Degradat	_	Time (da	ays)	Method		Evaluatio	on	Note
No information available No information available		-			formatio ble	n -		
12.3. Bio	accumul	ative potent	ial					
Oc	tanol-wa	ter partition	coefficien	t (log Kow)				



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	Diagon		: F4	(BCE)								
	1	entrat	ion Factor				**************************************					
Va			Species			thod		Evaluation			Note	
No infor available		No ir availa	nformatior able	1	No inform available	nation		informatio iilable	n	-		
	Chronic	ecoto	xicity									
	Value		Dose	Expos tim		Species		Method	Eva	aluation	No	te
Chronic	toxicity o	n fish	LC ₅₀	No informa availabl	1	ormatior ailable	1	ormation ilable	No infor avail	mation able	-	
	toxicity o a (Daphn		EC ₅₀	No informa availabl		ormatior ailable		ormation ilable	No infor avail	mation able	-	
12.4.	Mobility Known			ribution i	n environm	ental co	mpartme	ents:				
	Surface	tensio	n:									
	Value)	°C	С	Concentratio	n	Me	ethod			Note	
	No informa n availa	tio ir	lo nformatior vailable		No information No ir		informa ailable	nformation				
	Adsorp	tion / c	desorption	l								
Transpoi	rt i		efficient constant	lo	og Kow	•	oration ate	Me	ethod	***************************************	Note	
Soil-wate		inforn ilable	nation	No ir avail	nformation able	No inform availal		No infor		-		
Water-ai		inforn ilable	nation	No ir avail	nformation able	No inform availal	ation	No infor		-		



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Soil-air		information ilable	No information available	No informat available		No information available	-		
		of PBT and vPvB a							
			•			to be either persistent, vPvB) at levels of 0.1%		/e	
12.6. E	ndocrin	ne disrupting prop	erties						
p	properti	es according to RI		r Commis	sion D	ered to have endocrine elegated regulation (El gher.		r	
12.7.	Other ac	lverse effects							
r	No infor	mation available							
SECTION	13. Disp	oosal considerati	ons						
13.1. V	Vaste tr	eatment methods							
13.1.1.	Produc	ct/Packaging dispo	osal:						
	Submit Protect	•	ne legal person auth	orized by	the M	linistry of Environment	al and Nature		
12.1.2	\\/			.					
13.1.2.			gnations according according to official		nc				
	Dispos	al must be made a	according to official	regulatio	115.				
13.1.3.	Waste	treatment – releva	ant information:						
		ormation available							
13.1.4.	Sewage	e disposal – releva	ant information:						
	Waste	must not be dispo	osed of into the sew	age syste	m.				
		·							
13.1.5.	Other	disposal recomme	endations:						
	author	ized by the minist		t dispose	of the	stem. Submit the rema packaging into the sev inistry in charge.		ctors	
13.1.6.	Releva	nt Community pro	ovisions:						
	-								



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SECTION 14. Transport information	
Transporting/shipment by roa	d (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 inla	and waterways (ADN)
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 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):	-



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Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Further information: -	

15.1.	. Safety, health and environmental regulations/legislation specific for the substance or mixture						
	EU regulations						
	Authorisation and/or restrictions on use						
	Authorisations: -						
	Restrictions:	-					
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EC) No 793/9 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEc and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 200 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 safet 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 10 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);					
	Information according 1 guideline)	999/13/EC about limitation of emissions of volatile organic compounds (VOC-					
	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values 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						
5.2.	Chemical safety assessm	ent					

SECTION 16. Other information



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Trade name:	EOSIN Y, ISOTONIC SOLUTION					
Product code:	EIO-OT-X**	Date of compilation:	14 November 2022	Version:	4	

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:	Manufacturer's MSDS file.
16.4.	Classification and procedu 1272/2008 (CLP)	re used to derive the classification for mixture according to Regulation (EC)
Classific	ation	Classification procedure
_		-
16.5.	Relevant H statements (nu	mber and full text)
	H: 317	May cause an allergic skin reaction.
16.6.	Training advice:	-
16.7. Further information:		"X" in the product code marks different volumes (different packaging of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX: Exp	osure scenari	o resulting to	Chemical safe	ty assessment	



Page 1 of 16

Trading name:	NIGROSINE, ISOTONIC SOLUTION					
Product code:	NIO-X**	Date of compilation:	14 November 2022	Version: 4		

SECTI	ON 1: Identification of	the substan	ce/mixture a	and of the company/undertaking		
1.1.	Product identifier	Product identifier				
	Trading name:	NIGROSIN	E, ISOTONIC	SOLUTION		
	Chemical name:	-				
	Catalogue number:	NIO-OT-X	NIO-OT-X**			
1.2.	Relevant identified use	es of the sub	stance or mi	xture and uses advised against		
	Uses:	solution of nigrosine used with Eosin and nigrosine vital kit.				
	Uses advised against: Only the identified uses are			dentified uses are advised.		
	Reason why uses advi	sed against:	device, re	uct is intended for use only as an <i>in vitro</i> diagnostic medical gistered at the Agency for Medicinal Products and Medical and there is no reason to use it for other purposes		
1.3.	Details of the supplier	of the safety	/ data sheet			
	Supplier:	Е	BioGnost Ltd.			
	Address:	N	Medjugorska	59, Zagreb		
	Telephone number:	-	+385 1 24099	385 1 2409997		
	Fax no.:	-	+385 1 2404039			
	e-mail of competent p	erson: <u>r</u>	on: <u>msds@biognost.hr</u>			
	National contact:					
1.4.	Emergency telephone	Emergency telephone number				
	National Protection ar	nd Rescue Di	rectorate:	112		
	Medical information:			+385 1 2348 342		
	Other information:			-		

SECTIO	SECTION 2. Hazards identification					
2.1.	Classification of the substance of	Classification of the substance or mixture				
2.1.1.	Classification according to Regu	ulation (EC) No 12	72/2008 (CLP)			
	Hazard class and catego	ory code:	Hazard statements*:			
	Not identified as hazardous substance					
2.1.2.	Additional information					
	-					
*For ful	ll text of Hazard- and EU Hazard-s	statements: see Se	ection 16			
2.2.	Label elements					
	Product identification:	NIGROSINE, IS	SOTONIC SOLUTION			
	Identification number: -					
	Authorization no.:	-				
	Hazard pictograms:	-				



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Trading name:	NIGROSINE, ISOTONIC SOLUTION					
Product code:	NIO-X**	Date of compilation: 14	1 November 2022	Version: 4		

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

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

SECTI	SECTION 4. First aid measures						
4.1.	Description of first aid measu	ures					
	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 ai	der: Treat symptomatically.					
4.2.	Most important symptoms a	nd effects, both acute and delayed					
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.					
	Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Lonterm exposure may cause drying, cracking and tingling sensation of skin.					
	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.					



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Trading name:	NIGROSINE, ISOTONIC SOLUTION					
Product code:	NIO-X**	Date of compilation: 14 November 2022	Version: 4			

	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		
	-		

SECTI	SECTION 5. Firefighting measures				
5.1.	Extinguishing media				
	Suitable extinguishing media: Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam				
	Unsuitable extinguishing media: water jet				
5.2.	Special hazards arising from the substance or mixture				
	Hazardous combustion products: No information available				
5.3.	Advice for firefighters				
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.				
5.4.	Additional information				
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.				

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



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Trading name:	NIGROSINE, ISOTONIC SOLUTION			
Product code:	NIO-X**	Date of compilation:	14 November 2022	Version: 4

6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and and involved materials with water.		
6.3.3.	Other information:	-		
6.4.	Reference to other sections			
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.			

7.1.	Precautions for safe handling					
7.1.1.	Protection measures					
	Measures to prevent fire:		Keep away from sources of heat and ignition. Do not smoke.			
	Measures to prevent aerosol and dust generati	ion:	Secure proper ventilation.			
	Measures to protect the environment:		Prevent spilling into the sewage system and waterways.			
	Other measures:		-			
7.1.2.	Advice on general occupational hygiene:					
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.					
7.2.	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:	Mar	anufacturer's original packaging.			
	Requirements for storage rooms and vessels:		eep away from food and drink. Keep the containers ghtly closed.			
	Advices for storage equipment: be a		storage must be made of hard material; floors must resistant to chemicals. There must be no drain that ctly leads into sewage system. Secure proper tilation.			
	Further information on storage conditions:	and che	not place the unused material in the storage room do not use empty containers for storing other micals. Do not store with incompatible materials (see tion 9).			



Soil (agricultural)

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

amended by Regulation (EU) No. 1907/2006

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Trading name:			N	IIGROSINE, IS	SOTONIC SOI	LUTION		
Product code:	NIO-X** Date of			of compilation	n: 14 Nover	nber 2022	Version:	4
Recomme	ndations:							
		cific solution	ns:	_				
SECTION 8. Expos	ure contr	ols/persona	al protec	tion				
8.1. Control pa								
Substance		CAS I	No		exposure limit t term values		gical limit valu	ıes
				ppm	mg/m³		3	
-		-		-	-	No informat	tion available	
Substance - name:								
EC No: -		CAS No:	-					
DNEL								
				Industrial				
Davida of average		Acute Ac		Acute	Chro	nic	Chronic	2
Route of exposure:	effe	ect local effec		ect systemic	ystemic effect lo		effect syste	emic
Oral	-		-		-	-		
Inhalation	-		-		-	-		
Dermal	-		-		-	-		
Critical physical par	ameters:	solubility, fla	mmabili	ty, corrosivity:	-			
			1	Consumer				
Route of exposure:		Acute			Chronic		Chronic	
-	effe	ect local	t local effect system		effect l	ocal	effect syste	emic
Oral	-		-		-	-		
Inhalation	-		-		-	-		
Dermal	-		-		-	-		
PNEC				1				
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 info	No information available			

No information available



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Trading name:		NIGROSINE, ISOTONIC SOLUTION
Product code:	NIO-X**	Date of compilation: 14 November 2022 Version: 4

Air			No information available		
8.2.	Exposure controls				
8.2.1.	Appropriate engineering controls				
	Substance/mixture relate measures to prevent exp during identified uses:		Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.		
	Structural measures to preserve exposure:	revent	No information available		
	Organisational measures prevent exposure:	to	Organization of work in order to reduce other worker's influence during work process.		
	Technical measures to pr exposure:	event	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.		
8.2.2.	Personal protection equi	pment			
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.			
8.2.2.2.	Skin protection				
	Hand protection:		ctive gloves must be according to the EU Directive 2016/425/EEC and ard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min		
	Other skin protection:		antistatic clothing made of natural fibers (such as cotton) with long es (EN 13034), and shoes that cover the entire foot (EN 10335).		
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) acording to EN 14387) used when concentration levels exceed GVI.			
8.2.2.4.	Thermal hazards:	No in	formation available		
8.2.3.	Environmental exposure	controls			
	Substance/mixture related measures to prevent exposure:		See Section 6		
	Structural measures to prevent exposure:		Use modern equipment.		
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.		
	Technical measures to pr exposure:	event	See Section 6		

SECTION 9. Physical and chemical properties



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Trading name:		NIGROSINE, ISOTONIC SOLUTION	
Product code:	NIO-X**	Date of compilation: 14 November 2022	Version: 4

	Value	Method	
Physical state:	liquid	No information available	
Color:	black	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	

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

SECTION 11. Toxicological information



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Trading name:	NIGROSINE, ISOTONIC SOLUTION					
Product code:	NIO-X**	Date of compilation: 14 November 2022 Version: 4				

Acute toxici	ty:						
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure t	ime	Results	
Oral exposure:	No information available	-	LD ₅₀	-		-	
Dermal exposure:	No information available	-	LD ₅₀	_		-	
Inhalation exposure:	No information available	-	LC ₅₀	-		-	
Specific targ	get organ toxicity – si	ngle exposure (STOT SE):				
	Specif	ic effects	Target	organ		Note	
Oral exposure:	No information	available	No information	on available	-		
Dermal exposure:	No information	available	No information available -				
Inhalation exposure:	No information	available	No information available -				
Aspiration h	d corrosion:	TVO IIIIOI	rmation available				
i i	Exposure time	Species	Evaluation	Method		Note	
Skin irritation:	-	-	-				
Eye irritation:	-	-	-				
Sensitization	n						
•	No information avail	able					
Inhalation exposure:	No information avail	able					
Symptoms r	related to the physica	l, chemical and	toxicological chara	cteristics			
Oral exposure:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.						
Dermal exposure:	: -	•	ure, resorption effe		ely. Long	-term exposu	



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Trading name:		NIGROSINE, ISOTONIC SOLUTION					
Product code:	NIO-X**	Date of compilation: 14 November 2022	Version: 4				

innalation expositre.		large amounts eezing, heada	•		adequately vent	ilated perim	eter may cause	
Eye exposure: Direct eye co sensation.		ntact may cause slight to moderate irritation, lacrimation and burning						
Reneate	ed dose	toxicity (sub	acute, subchro	onic chron	ic)			
Nepeute		Dose	Exposure time	Species	10)	Method	Evaluation	n Note
Subacute oral	No availa	information able	No information available	No informati available	_	No information available	No informatio available	on -
Subacute dermal	No availa	information able	No information available	No informat available		No information available	No informatio available	on -
Subacute inhalation	No availa	information able	No information available	No informati available	_	No information available	No informatio available	on -
Subchronic oral	No availa	information able	No information available	No informat available	-	No information available	No informatio available	on -
Subchronic dermal	No availa	information able	No information available	No informat available	_	No information available	No informatio available	on -
Subchronic inhalation	No availa	information able	No information available	No informat available	-	No information available	No informatio available	on -
Chronic oral	No availa	information able	No information available	No informat available	_	No information available	No informatio available	on -
Chronic dermal	No availa	information able	No information available	No informat available		No information available	No informatio available	on -
Chronic inhalation	No availa	information able	No information available	No informati available		No information available	No informatio available	on -
C:					TOT :),		
Specific	target		y – repeated e pecific effects	xposure (S	1011		an .	Note
Subacute oral			tion available		Target organ No information available		- Note	
Subacute dermal			tion available					_
Subacute inhalat			tion available			nformation avai		_



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Trading name:	NIGROSINE, ISOTONIC SOLUTION					
Product code:	NIO-X**	Date of compilation: 14 November 2022	Version: 4			
Product code.	INIO-X	Date of compilation. 14 November 2022	version. 4			

			<u> </u>				
Subchro	onic oral	No information	n available	No information available	_		
	onic dermal No information			No information available	-		
	onic inhalation	No information		No information available			
Chronic		No informatio		No information available			
Chronic	dermal	No informatio	n available	No information available	-		
Chronic	inhalation	No informatio	n available	No information available	-		
		·		·	:		
	CMR effects (c	arcinogenicity; m	utagenicity; repro	oductive toxicity)			
	Carcinogenicit	y:	Current studies on test animals did not indicate carcinogenic effects.				
	Mutagenicity in-vitro:		Current in vitro tests did not indicate mutagenic effects.				
	Genotoxicity:		No information available				
	Mutagenicity i	n-vivo:	Current <i>in vivo</i> tests did not indicate mutagenic effects. No information available No toxicity on reproductive organs was determined in reproductive organs.				
	Germ cell muta	agenicity:					
	Reproductive t	oxicity:					
	Summary of ev	valuation of the (CMR properties:	-			
11.2.	Information or	other hazards:					
11.2.1.	Endocrine disr	upting propertie	5:				
	No known end	ocrine disrupting	properties that a	affect human health.			
11.2.2.	Other informat	tion:					

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

SECTION 12. Ecologi	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			



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Trading name:	NIGROSINE, ISOTONIC SOLUTION					
Product code:	NIO-X**	Date of compilation:	14 November 2022	Version: 4		

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						
Marina									

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

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

12.3.	RIOS	Bloaccumulative potential					
	Octanol-water partition coefficient (log Kow)						
Valu	ıe	Concentration	рН	°C	Method	Evaluation	Note
_		No information available	-	-	No information available	No information available	-

Bioconcen	tration factor (BCF)			
Value	Species	Method	Evaluation	Note



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Trading	g nam	e:	NIGROSINE, ISOTONIC SOLU					SOLUTIO	N				
Produc	t code	e: N	IO-X**	D	ate of co	mpil	ation:	14 No	vember 2	2022	,	Version:	4
No information No inform available available		nation No information available		No information available			No information available		n				
	Chror	nic ecoto	xicity										
	Valu	ıe	Dose		osure ime	Sp	ecies	Met	hod	Eva	luatio	n	Note
Chronic	toxicit	ty on fish	LC ₅₀	No infor availa	mation	No infor availa	mation able	No informa availab				1 –	
Chronic crustace		-	EC ₅₀	No infor availa	mation	No infor availa	mation able	No informa availab	ation	No inforn availa	nation ble	 	
12.4.	Mobi	lity in soi	il										
		-	dicted distributi	on in e	environme	ntal o	compart	ments:					
	No in	formatio	n available										
	Surfa	ce tensio	n:										
	Va	alue	°C	Concentration Method			Note						
	No inforr availa	mation able	No information available		informati ailable	on	No infa	ormatior ole	ation _				
	Adso	rption / o	desorption										
Transpo	ort		coefficient 's constant	log Kow		Ev	vaporatio	aporation rate M		Method		No	ote
Soil-wa	tor :	No available	information	No ir availa	nformatior able		o inform vailable	mation No informavailable		_		-	
Water-a	air 🗀	No available			nformatior able		No information available		No information available		on	-	
Soil-air		No available	information	No ir availa	nformatior able		o inform ailable	ation	No infor		on	-	
12.5.	ъ.		and vPvB asses										



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Trading name:		NIGROSINE, ISO	TONIC SOLUTION	
Product code:	NIO-X**	Date of compilation:	14 November 2022	Version: 4

12.6.	Endocrine disrupting properties					
	No known endocrine disrupting p	properties that affect the environment.				
12.7.	Other adverse effects					
	No adverse effects are expected.					
SECTION	l 13. Disposal considerations					
13.1.	Waste treatment methods					
	:					
13.1.1.	Product/Packaging disposal:					
	Submit for disposal to the legal Protection.	person authorized by the Ministry of Environmental and Nature				
13.1.2.	Waste codes/waste designation	s according to Law:				
	No information available					
13.1.3.	Waste treatment – relevant info	rmation:				
	No information available					
	:					
13.1.4.	Sewage disposal – relevant info	rmation:				
	Waste must not be disposed of into the sewage system.					
13.1.5.	Other disposal recommendation	ns:				
	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	SECTION 14. Transport information					
	Transporting/shipment by road (A	ADR)				
UN numl	ber:	Not subject to transport regulations.				
UN prop	er shipping name:	-				
Transpor	t hazard class(es):	-				



SAFETY DATA SHEET

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

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Trading name:		NIGROSINE, ISOTONIC SOLUTION						
Product code:	NIO-X**	Date of compilation:	14 November 2022	Version:	4			
Packing group:		-						
Environmentally has		-						
Special precautions		-						
<u> </u>	ng/shipment by r							
UN number:		Not subject to transport	regulations.					
UN proper shipping		-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally has	zardous:	-						
Special precautions	for user:	-						
Inland wat	erway transport (ADN)						
UN number:		Not subject to transport	regulations.					
UN proper shipping	name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally haz	zardous:	-						
Special precautions	for user:	-						
Transporti	ng/shipment by s	ea (IMDG)						
UN number:		Not subject to transport	regulations.					
UN proper shipping	յ name:	-						
Transport hazard cl	ass(es):	-						
Packing group:		-						
Environmentally has	zardous:	-						
Special precautions	for user:	-						
Transporti	ng/shipment by a	nir (ICAO-TI/IATA-DGR)						
UN number:		Not subject to transport	regulations.					
UN proper shipping name:								
Transport hazard class(es):		_						
Packing group:		_						
Environmentally ha	zardous:							
Special precautions for user:		_						



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Trading name:	NIGROSINE, ISOTONIC SOLUTION		
Product code:	NIO-X**	Date of compilation: 14 November 2022	Version: 4

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

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



SAFETY DATA SHEET

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

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Trading name:	NIGROSINE, ISOTONIC SOLUTION			
Product code:	NIO-X**	Date of compilation: 14 November 2022	Version: 4	

16.4.	4. Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)			
Classifi	cation	Classification procedure		
-		-		
16.5.	Relevant H statements (num	ber and full text)		
	H: -	-		
16.6.	Training advice:	-		
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.		

ANNEX: Exposure scenario resulting to Chemical safety assessment