

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		

SECTIO	ON 1: Identification of the	e substa	nce/r	mixture and	of the company/undertaking	
1.1.	Product identifier					
	Trading name: E	OSIN Y,	ISOT	ONIC SOLUTI	ON	
	Chemical name: -	-				
	Product code: E	uct code: EIO-OT-X**				
1.2.	Relevant identified uses of the substance or m			ance or mixtu	re and uses advised against	
	Uses: Uses advised against:			Aqueous so kit.	lution of Eosin Y used with Eosin and nigrosin vital	
				Only the ide	entified uses are advised.	
				t is intended for use only as an <i>in vitro</i> diagnostic vice and there is no reason to use it for other		
1.3.	Details of the supplier of the safety data sheet					
	Supplier:		BioGr	Snost Ltd.		
	Address:		Medj	djugorska 59, Zagreb		
	Telephone number:		+385	5 1 2409997		
	Telefax:		+385	35 1 2404039		
	e-mail of competent pe	erson:	<u>msds</u>	sds@biognost.hr		
	National contact:		-			
1.4.	Emergency telephone r	numbers				
	National Protection and	d Rescue	e Direc	ctorate:	112	
	Medical information:				+385 1 2348 342	
	Other information:				-	

SECTION 2. Hazards identification						
2.1.	Classification of the substance	e or mixture				
2.1.1.	Classification according to Re	egulation (EC) No 1	272/2008 (CLP)			
	Hazard class and category code: Hazard statement*:					
	Skin. Sens. 1		H317			
2.1.2.	Additional information					
	-					
*For the	full text of H and EUH phrases	see Section 16.				
2.2.	Label elements					
	Product identification:	ation: 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. 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			

SECTION 4. First aid measures				
4.1.	Description of first aid me	easures		
	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 symptoms 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	ate medical attention and special treatment needed			
	Treat symptomatically.				

SECTIO	ON 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.	ibstance 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 c containers exposed to fire with wa	ompressed air breathing apparatus and fireproof clothing. Cool closed ter spray or vapor.			
5.4.	Additional information				
	U	king due to increase in pressure. Remove sources of heat and environment with extinguishing media.			

SECTIC	SECTION 6. Accidental release measures					
6.1.	Personal precautions, protective	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 of inadequate ventilation use adequate airways protective equipment (see Section 8).					



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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 containment 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			
	-			

Precautions for safe handling				
Protection measures				
Measures to prevent fire:		n well ventilated storage rooms. Refer e manufacturer's recommendations.		
Measures to prevent aerosol and dust generation	n: Secu	re proper ventilation.		
Measures to protect the environment:		ent spilling into the sewage system vaterways.		
Other measures:	-			
Advice on general occupational hygiene:				
Do 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:	well ventilated s	ep in tightly closed and upright set containers in a Il ventilated storage rooms at temperatures ging from 15 to 25 °C.		
Packaging materials:	Manufacturer's original packaging.			
Requirements for storage rooms and vessels:	Keep away from tightly closed.	Keep away from food and drink. Keep the containers tightly closed.		
Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.			
Further information on storage conditions:	and do not use	e unused material in the storage room empty containers for storing other ot store with incompatible materials		
	Measures to prevent aerosol and dust generatio Measures to protect the environment: Other measures: Advice on general occupational hygiene: Do not eat, drink or smoke in the workspace. The Conditions for safe storage, including any incom Technical measures and storage conditions: Packaging materials: Requirements for storage rooms and vessels: Advices for storage equipment:	Measures to prevent fire:to theMeasures to prevent aerosol and dust generation:SecureMeasures to protect the environment:Preve and voltageOther measures:-Advice on general occupational hygiene:-Do not eat, drink or smoke in the workspace. Thoroughly wash had-Conditions for safe storage, including any incompatibilitiesKeep in tightly or well ventilated so ranging from 15Packaging materials:Manufacturer's or tightly closed.Requirements for storage rooms and vessels:Keep away from tightly closed.Advices for storage equipment:The storage must must be resistand drain that direct proper ventilationFurther information on storage conditions:Do not place the and do not use or chemicals. Do not (see Section 9).		



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Re	ecommendations:	-
In	ndustrial sector specific solutions:	-

SECTION 8. E	XPOSU	RE COI	NTROLS / P	PERSON/	AL PROTECT	ION		
8.1. Con	trol para	ameter	S		ſ			
Subst	ance		CAS	No		cupational exposure limit alues/short term values		Biological limit values
					ppm		mg/m ³	
-		-		-		-	-	
Substance:	ubstance: -							
EC No:	-		CAS No:	-				
DNEL				1				
					Industria	al		
Route of exposure:			ute effect ystemic		Chronic eff local	fect Chronic effect systemic		
Oral -		-		-		-		-
Inhalation -			-		-		-	
Dermal -			-		-		-	
Critical physic	al paran	neters:	solubility, fl	ammabil	ity, corrosivi	ty:	-	
					Consume	er		
Route of expo	osure:		te effect ocal		ute effect ystemic		Chronic eff local	fect Chronic effect systemic
Oral		-		-		-		-
Inhalation		-		-		-		-
Dermal		-		-		-		-
PNEC								
Environmenta	l protect	tion tai	rget		PNE	с		
Fresh water					No ir	No information available		
Freshwater se	diments				No ir	No information available		
Marine water					No ir	No information available		
Marine sedim	ents				No ir	nforma	ation availabl	e
Food chain					No ir	nforma	ation availabl	e
Microorganisr	ms in sev	wage ti	reatment			No information available		
Soil (agricultu	ral)						ation availabl	
Air					No ir	nforma	ation availabl	e



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

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8.2.	Exposure controls					
8.2.1.	Appropriate engineering controls	;				
	Substance/mixture related measu to prevent exposure during ident uses:		Use personal protective equipment. Do not eat, drink or smoke in the workspace.			
	Structural measures to prevent exposure:		No information available			
	Organisational measures to preve exposure:	ent	Organization of work in order to reduce other worker's influence during work process.			
	Technical measures to prevent exposure:		Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.			
8.2.2.	Personal protection equipment:					
8.2.2.1.	Eye and face protection:		Safety glasses 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 S	Section 6			
	Structural measures to prevent exposure:	Use ı	modern equipment.			
	Organisational measures to prevent exposure:	•	ot the work process to the required working conditions of the place.			
	Technical measures to prevent exposure:	See S	Section 6			

SECTIO	SECTION 9. Physical and chemical properties				
9.1.	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
	Lover 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	N 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).



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11.1.	Informatio	on on to	kicological et	fects						
	Acute tox	icity:								
Route of exposure		Me	ethod	Sp	ecies	Effec Do LD ₅₀ /Lu ATE _m	se C ₅₀ or	Exposure time		Results
Oral:		-	No information - i available				o nation able	-		-
Dermal:			ormation iilable		-	No inform availa	nation	-		-
Inhalatic	n:		No information available - information available						-	
	Specific ta	arget org	an toxicity -			fot-se):				
			Specific effects				Target organ			Note
Oral:			No information available				-		-	
Dermal:			No information available				-		-	
Inhalatic	on:	No info	rmation avai	lable		-			-	
	Aspiration	n hazard:	:		-					
	Irritation	and corre	osion							
	·		Exposure	time	Specie	es	Evaluati	on M	lethod	Note
Skin cor	rosion/irrita	ntion:	No infor available	mation	rabbit -		-			mild skin irritation
Serious i	rritation to	eyes:	No infor available	mation				-		-
	Sensitizat	ion								
Skin sen	sitization:	1	information	available	2					
Respirat sensitiza	ory		information							
	Symptom	s related	l to physical,	chemica	al and toxic	ological	nroperti	۹۲		
Oral exp						.e.egicai j	. oper m			
Oral exposure: No known specific syn				mptomb.						



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Inhalation expo Eye exposure:	sure:		known specific symptoms. known specific symptoms.							
		1								
Repea	ated dose	toxicity (subacute, subcł	hronic, chron	ic)					
	Do	se	Exposure time	Species	Method	Evaluation	Note			
Subacute oral	No info available		No information available	No information available	No information available	No informatio available	No information available			
Subacute dermal	No info available		No information available	No information available	No information available	No informatio available	No information available			
Subacute inhalation	No info available		No information available	No information available	No information available	information informatio				
Subchronic oral	No info available		No information available	No information available	No information available	No informatio available	No information available			
Subchronic dermal	No info available		No information available	No information available	No information available	No informatio available	No information available			
Subchronic inhalation	No info available		No information available	No information available	No information available	No informatio available	No information available			
Chronic oral	No info available		No information available	No information available	No information available	No informatio available	No information available			
Chronic dermal	No info available		No information available	No information available	No information available	No informatio available	No information available			
Chronic inhalation	No info available		No information available	No information available	No information available	No informatio available	No information available			
Speci	fic target o	organ tox	kicity - repeated				N1 /			
Subacute oral		N	Specific effects No information available		Target of No information a	-	Note No information available			
Subacute derma	al	N	o information a	vailable	No information a	vailable	No information available			



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

	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 <i>in-vivo</i> :	Based on available data, the classification criteria are not met.					
	Germ cell mutagenicity:	Based on available data, the classification criteria are not met.					
	Reproductive toxicity:	Based on available data, the classification criteria are not met.					
	Summary of evaluation of the CMR properties:	No information available					
11.2.	Information on other hazards:						
11.2.1.	Endocrine disrupting properties:						
	No known endocrine disrupting properties that affect human health.						
11.2.2.	Other informations:						
	-						

SECTION 12. Ecological information							
12.1.	Toxicity						



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Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	-	-
Crustacea:	EC ₅₀	48 hours	-	-	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	-	-	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	-	-
Crustacea:	EC ₅₀	48 hours	-	-	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	-	-	-
Other organisms	-	-	-	-	-	-

12.2. Persistence and degradability

	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	-

Biodeg	radation	1	i	1
% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

12.3. Bioaccumulative potential

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



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	Biocor	ncentrat	ion Factor	(BCF)								
Va	lue		Species		Me	thod		Evaluation			Note	
No infor		No i	nformatior		No inform		No	information			Hote	
available	е	avail	able		available		avai	lable		-		
	Chron	nic ecoto	xicity									
	Value		Dose	Expos tim		Species	N	/lethod	Ev	aluation	Not	te
Chronic	Chronic toxicity on fish LC ₅₀ i		No informa availabl		ormation iilable		rmation lable	No information available		-		
	Chronic toxicity on crustacea (Daphpia) EC ₅₀ i			No No information info available ava		information		No information available		-		
12.4.	Mobili	ity in soi	1									
				ribution i	n environm	ental com	partme	nts:				
	Surfac	e tensio	n:	I								
	Valu		°C		Concentration		Method		Note			
	No inform n avail	natio i	No nformatior Ivailable		No information No in available available		nformation able		_			
	Adcor	ntion (docorption									
	Ausor		desorptior pefficient	I		Evapor	ation					
Transpo	ort		s constant	lo	og Kow	rate		Me	thod		Note	
Soil-wat		lo inforr vailable	nation	No ir availa	nformation able	No informat available		No inforn available	natior	1 -		
Water-a		lo inforr vailable	nation	No ir availa	nformation able	No informat available		No inforn available	natior	1 -		



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Trada nama		Page 13 of 16							
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		No information No available inform availal			No information available	-			
12.5.	Results	of PBT and vPvB as	sessment						
	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.							ve	
12.6.	Endocri	ne disrupting prop	erties						
	properti	ies according to RE		r Commis	sion De	red to have endocrine elegated regulation (E her.	1 5	or	
12.7.	Other a	dverse effects							
	No info	rmation available							
	1								
SECTION	N 13. Dis	posal consideration	ons						
13.1.	Waste ti	reatment methods							
13.1.1.	Produ	ct/Packaging dispo	osal:						
	Submi Protec	•	e legal person autł	norized by	the M	inistry of Environment	tal and Nature		
13.1.2.	Waste	codes/waste desig	gnations according	to Law:					
			according to officia		ons.				
13.1.3.		treatment – releva							
	No inf	ormation available							
13.1.4.	Sewag	je disposal – releva	int information:						
Waste must not be disposed of into the sewage system.									
13.1.5.	Other disposal recommendations:								
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.								
13.1.6.	Releva	ant Community pro	ovisions:						
	-								



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SECTION 14. Transport information	
Transporting/shipment by roa	
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 rai	l (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	a (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 informat	ion: -								

15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture				
	EU regulations				
	Authorisation and/or res	strictions 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 (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 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 			
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC- guideline)				
	National legislation: Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act				
15.2.	Chemical safety assessm	ient			

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 procedur 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: Exposure scenario resulting to Chemical safety assessment

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

SECTIO	ON 1: Identification of th	e substance	e/mixture a	and of the company/undertaking		
1.1.	Product identifier					
	Trading name: NIGROSI		, ISOTONIC	SOLUTION		
	Chemical name:	-				
	Catalogue number:	NIO-OT-X**	ł			
1.2.	Relevant identified uses	of the subs	tance or mi	xture and uses advised against		
	Uses:		Aqueous s kit.	solution of nigrosine used with Eosin and nigrosine vital		
	Uses advised against:		Only the i	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, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes 			
1.3.	Details of the supplier of the safety data sheet					
	Supplier:	Bi	lioGnost Ltd.			
	Address:	М	Medjugorska 59, Zagreb			
	Telephone number: +		+385 1 2409997			
	Fax no.:	+3	+385 1 2404039			
	e-mail of competent pe	rson: <u>m</u>	msds@biognost.hr			
	National contact:	-	•			
1.4.	Emergency telephone n	umber				
	National Protection and Rescue Dire		ectorate:	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 Regula	tion (EC) No 12	72/2008 (CLP)		
	Hazard class and category code: Hazard statements*:				
	Not identified as hazardous substa	ance.	-		
2.1.2.	Additional information				
	-				
*For ful	l text of Hazard- and EU Hazard-sta	tements: see S	ection 16		
2.2.	Label elements				
	Product identification:	NIGROSINE, I	SOTONIC SOLUTION		
	Identification number: -				
	Authorization no.:	-			



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

	Hazard pictograms:	-
	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	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 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 aide	r: Treat symptomatically.		
4.2.	Most important symptoms and effects, both acute and delayed			
	Following inhalation.	nhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.		
	Following skin contact.	Slight irritation. After short exposure, resorption effects are not likely. Long- erm exposure may cause drying, cracking and tingling sensation of skin.		



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Trading name:	me: NIGROSINE, ISOTONIC SOLUTION					
Product code:	NIO-X**	Date of compilation:	14 November 2022	Version: 4		
Following eve contact:		Direct eye contact may caus	e slight to moderate irritat	tion, lacrimation and		

	Following eye contact:	burning sensation.			
	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.			
4.3.	Indication of any immediate medical attention and special treatment needed				
	-				

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

SECTIO	ON 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 Se	ection 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 containn	nent and cleaning up				



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

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

SECTION 7. Handling and storage					
7.1.	Precautions for safe handling				
7.1.1.	Protection measures				
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.			
	Measures to prevent aerosol and dust generati	on: 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. T	horoughly wash hands after work and before eating.			
7.2.	Conditions for safe storage, including any inco	npatibilities			
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.			
	Packaging materials:	Manufacturer's original packaging.			
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.			
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.			



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

	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposur	e contro	ols/persona	al protec	tion			
8.1. Control para	meters						
Substance CAS No		No	Occupational exposure limit values/short term values		Biolog	Biological limit values	
				ppm	mg/m ³	-	
-		-		-	-	No informa	tion available
Substance							
EC No: -		CAS No:	-				
DNEL							
				Industrial			
Route of exposure:	A	Acute Ac		Acute	te Chroni		Chronic
Route of exposure.	effe	ct local	effect systemic		effect lo	ocal	effect systemic
Oral	-		-		-	-	
Inhalation	-		-		-	-	
Dermal	-		-		-	-	
Critical physical parar	neters: s	olubility, fla	mmabilit	ty, corrosivity:	-		
				Consumer			
Route of exposure:		cute ct local	Acute effect systemic		Chron effect lo		Chronic effect systemic
Oral	-		-		-	-	
Inhalation	-		-		-	-	
Dermal	-		-		-	-	
PNEC							
Environmental protection target				PNEC	PNEC		
Fresh water			No infor	No information available			
Freshwater sediments			No infor	No information available			
Marine water				No infor	No information available		



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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			

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

8.2.	Exposure controls					
8.2.1.	Appropriate engineering controls					
	Substance/mixture relate measures to prevent expe 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 pr 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					
			tive gloves must be according to the EU Directive 2016/425/EEC and and 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 s (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 inf	ormation available			
8.2.3.	Environmental exposure	controls				
	Substance/mixture relate measures to prevent expe		See Section 6			
	Structural measures to pr exposure:	revent	Use modern equipment.			
	Organisational measures prevent exposure:	to	Adapt the work process to the required working conditions of the workplace.			



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

Technical measures to prevent exposure:

See Section 6

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

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



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

10.6. Hazardous decomposition products: No information available.

11.1.	Informatio	n on hazard classes as	defined in Requ	lation (EC) No 12	72/2008		
	Acute toxic		denned in Regu		12,2000		
Route of Method Species		Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure	Exposure time		
Oral ex	(posure:	No information available	-	LD ₅₀	-		-
Derma	l exposure:	No information available	-	LD ₅₀	-		-
Inhalat exposu		No information available	-	LC ₅₀	-		-
	Specific tar	rget organ toxicity – si	ngle exposure (S	TOT SE):			
		Specif	ic effects	Targe	t organ		Note
Oral ex	(posure:	No information	available	No informati	No information available -		
Derma	l exposure:	No information	available	No informati	No information available -		
Inhalat	ion exposure	: No information	available	No informati	on available	-	
	Aspiration	hazard: nd corrosion:	No inform	nation available			
		Exposure time	Species	Evaluation	Method		Note
Skin irr	ritation:	-	-	-	-	-	
Eye irri	tation:	-	-	-	-	-	
	Sensitizatio	on					
Derma	l exposure:	No information avail	able				
Inhalat exposu	ion	No information avail	able				
	Symptoms	related to the physica	l, chemical and t	oxicological chara	acteristics		
Oral ex	(posure:	Swallowing may c sensation; higher In case of vomitin concentration ma	ause irritation of levels of concent g, aspiration cau	mucosa, tingling ration may cause ses coughing, diff	sensation in nausea, abd	ominal p	ain and vomitir



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Trading name:		NI	GROSINE, ISO	TONIC SOLU	ΓΙΟΝ	
Product code:	NIO-X**	Date o	f compilation:	14 Novemb	er 2022	Version: 4
Dermal exposure	• •	ation. After short drying, cracking	•	•	e not likely. Lo	ng-term exposure
Inhalation exposi	Iro.	of large amount sneezing, heada	•		ilated perime	ter may cause
Eye exposure:	Direct eye sensation.	contact may cau	ise slight to moo	derate irritation,	lacrimation a	nd burning
Repeate	d dose toxicity (s	ubacute, subchro	onic, chronic)			
· · · · ·	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No informatio available	n No information available	No information available	No information available	No informatior available	ı -
Subacute dermal	No informatio available	n No information available	No information available	No information available	No informatior available	ı -
Subacute inhalation	No informatio available	n No information available	No information available	No information available	No informatior available	ı -
Subchronic oral	No informatio available	n No information available	No information available	No information available	No informatior available	ı -
Subchronic dermal	No informatio available	n No information available	No information available	No information available	No information available	ı -
Subchronic inhalation	No informatio available	n No information available	No information available	No information available	No information available	ı -
Chronic oral	No informatio available	n No information available	No information available	No information available	No information available	ı -
Chronic dermal	No informatio available	n No information available	No information available	No information available	No information available	ı -
Chronic inhalation	No informatio available	n No information available	No information available	No information available	No informatior available	ı -
Specific	target organ toxi	· ·	exposure (STOT I			
		Specific effects		Target org	an	Note



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Trading	g name:		NIGRO	SINE, ISOTONIC SOLUTION				
Produc	t code:	NIO-X**	Date of com	npilation: 14 November 2022	Version: 4			
Subacu	te dermal	No informa	ition available	No information available	-			
Subacute inhalation No information		ition available	No information available	-				
Subchronic oral No information		tion available	No information available	-				
Subchronic dermal No information		tion available	No information available	-				
Subchronic inhalation No information		ition available	No information available	-				
Chronic oral No information		ition available	No information available	-				
Chronic dermal No informatio		ition available	No information available	-				
Chronic inhalation No information		tion available	No information available	-				
	Mutagenicity in-vitro: Genotoxicity: Mutagenicity in-vivo: Germ cell mutagenicity:		No information Current <i>in viv</i> No information	Current in vitro tests did not indicate mutagenic effects. No information available Current in vivo tests did not indicate mutagenic effects. No information available				
	Reproductive toxicity:		organs.	n reproductive organs was determ	ined in reproductive			
	Summary	of evaluation of th	ne CMR properties:	-				
11.2.	Informatio	on on other hazard	ds:					
11.2.1.	Endocrine	e disrupting prope	rties:					
	No knowi	n endocrine disrup	ting properties that	affect human health.				
	No known endocrine disrupting properties that affect human health. Other informations:							

SECTION 12. Ecological information							
12.1. Toxicity							
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note	
Fish	LC ₅₀	96 hours	No information available	No information available	-	-	
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-	
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-	
Microorganisms	LC ₅₀	72 hours	-	-	-	-	



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

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

12.2. Persistence and degradability

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

Biodegradation

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

12.3. Bioaccumulative potential

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

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

	Mobility in soil								
	Known or pree	dicted distributi	ion in environmen	tal compartments:					
	No informatio	n available							
	Surface tension:								
	Value	°C	Concentratio	n Metho	od	Note			
	No information available	formation information No information		No information available					
	Adapting (
Transpor	rt i	coefficient	log Kow	Evaporation rate	Method	Note			
1	rt A/D Henry	coefficient 's constant information	log Kow No information available	Evaporation rate No information available	Method No information available	Note			
Transpor	rt A/D Henry er No available	coefficient 's constant information information	No information	No information	No information				



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				Page 13 01 16		
Trading name:			NIGROSINE, ISOTONIC SOLUTION			
Product	t code:	NIO-X**	Date of compilation: 14 November 2022	Version: 4		
	No inform	ation available				
12.6.		disrupting proper				
	No known	endocrine disrup	ting properties that affect the environment.			
107		<i></i>				
12.7.		erse effects	at a d			
	No advers	e effects are expe	ected.			
SECTION	12 Dian	acal consideratio				
13.1.		osal consideratio				
15.1.	waste tr	eatment methods				
13.1.1.	Product	Packaging dispos	ali			
13.1.1.		5 5 .	legal person authorized by the Ministry of Environme	ntal and Nature		
	Protectic		legal person authorized by the Ministry of Environme			
	:					
13.1.2.	Waste co	odes/waste desigr	nations according to Law:			
	No infor	mation available				
13.1.3.	Waste tr	eatment – relevar	t information:			
	No infor	mation available				
13.1.4.	Sewage	disposal – relevan	t information:			
	Waste m	ust not be dispos	ed of into the sewage system.			
13.1.5.	Other di	sposal recommen	dations:			
		•	duct's remains into the sewage system. Submit the rer			
		• •	r in charge. Do not dispose of the packaging into the s			
the packaging to the collectors authorized by the ministry in charge. Do not dispose of in place ignition may occur.						
13.1.6.	Relevant	Community prov	isions:			
	-					
SECTION	N 14. Trans	sport informatio	n			
	Transporti	ng/shipment by r	pad (ADR)			
UN num	ber:		Not subject to transport regulations.			
UN prop	per shipping	g name:	-			
	in proper simpping name.					



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Trading name:	NIGROSINE, ISOTONIC SOLUTION				
Product code:	NIO-X**	Date of compilation:	14 November 2022	Version: 4	
	1		1		
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmentally ha	zardous:	-			
Special precautions	for user:	-			
Transporti	ng/shipment by rail (RID)			
UN number:		Not subject to transport	regulations.		
UN proper shipping	g name:	-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmentally ha	zardous:	-			
Special precautions	for user:	-			
Inland wat	erway transport (ADI	N)			
UN number:		Not subject to transport	regulations.		
UN proper shipping	g name:	-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmentally ha	zardous:	-			
Special precautions	for user:	-			
Transporti	ng/shipment by sea	(IMDG)			
UN number:		Not subject to transport	regulations.		
UN proper shipping	g name:	-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmentally ha	zardous:	-			
Special precautions	for user:	-			
Transporti	ng/shipment by air (l	CAO-TI/IATA-DGR)			
UN number:		Not subject to transport	regulations.		
UN proper shipping	g name:	-			
Transport hazard cl	ass(es):	-			
Packing group:		-			
Environmentally ha	zardous:	-			
Special precautions	for user:	-			
Further information	: The product	is not subject to classificatio	n.		



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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 restrictions 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 793/9. 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 2004 on the limitation of emissions of volatile organic compounds due to the use or organic solvents in certain paints and varnishes and vehicle refinishing products and amending 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 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		



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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

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

ANNEX: Exposure scenario resulting to Chemical safety assessment