

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

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Trading name:	ORANGE II, C.I. 15510			_	
Product code:	O2-P-X**	Revision date:	21 Dec 2022	Version:	3

1.1.	Product identifier			
	Substance name:	ORANGE II, C.I. 15510		
	EC No:	211-199-0		
	Synonyms:	Acid Orange	7	
	Catalogue number:	O2-P-X**		
	REACH registration number:	-		
	CAS No:	633-96-5		
	Index no.:	-		
1.2.	Relevant identified uses of th	e substance or	r mixture and uses advised against	
	Uses:		Used as a counterstain, as a substitute for Orange G.	
	Uses advised against:		Only the identified uses are advised.	
	Reason why uses advised aga	ainst:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device listed in the Registry of medical devices at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes	
1.3.	Details of the supplier of the safety data sheet			
	Supplier:		BioGnost Ltd.	
	Address:		Medjugorska 59, Zagreb	
	Telephone number:		+385 1 2409997	
	Fax no.:		+385 1 2404039	
	e-mail of competent person:		msds@biognost.hr	
	National contact person:		-	
1.4.	Emergency telephone number	Emergency telephone number		
	National Protection and Resc Directorate:	rue	112	
	Medical information:		+385 1 2348 342	
	Other information:		-	

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



General notes:

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*For fu	ıll text of Hazard- and EU Hazard-	statements: see Section 16
2.2.	Label elements	
	Product identification:	ORANGE II, C.I. 15510
	Identification number:	-
	Authorisation number:	-
	Hazard pictograms:	GHS07
	Signal word:	Warning
	Hazard statements:	H315 Causes skin irritation.H319 Causes serious eye irritation.H335 May cause respiratory irritation.
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/attention.
	Further information:	-
2.3.	Other hazards	
	Endocrine Disrupting Proper	ties:
	No known endocrine disruptin	g properties
	Results of PBT and vPvB asse PBT or a vPvB.	essment : According to the results of its assessment, this substance is not

5201.011 5.	Composition/info	iniacion on ingre			
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)	
633-96-5	211-199-0	-	Sodium 4-[(2-hydroxy-1-naphthyl)azo]benzenesulphonate	90-100%	
SECTION 4. First aid measures					



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	Following inhalation:		Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.
	Following skin contact:		Remove contaminated clothing. Immediately begin rinsing with copious amounts of water for at least 15 min. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:		Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.
	Following ingestion:		DO NOT induce vomiting. If the afflicted person is unconscious, do not provide them with anything orally. Drink at most two glasses of water. Seek medical assistance.
	Self-protection of the first	aider	-
4.2.	Most important symptoms	and effects, both	h acute and delayed
	Following inhalation:	Harmful if in	haled.
	After skin contact:	Harmful in c	ontact with skin.
	Following eye contact:	Risk of serio	us damage to eyes.
	Following ingestion:	Harmful if sv	vallowed.
4.3.	Indication of any immediat	e medical attent	ion and special treatment needed
	-		

SECTION	SECTION 5. Firefighting measures			
5.1.	Extinguishing media			
	Suitable extinguishing media:	Water, foam, dry powder, CO ₂		
	Unsuitable extinguishing media:	-		
5.2.	Special hazards arising from the substa	ance 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			
	Make sure the water used for extinguis waters system.	shing fire does not contaminate water surface or underground		

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures



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

SECTIO	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 ignition and heat. Do not use sparkling tools.		
	Measures to prevent aerosol and dust general	tion: Secure proper ventilation.		
	Environmental precautions:	Prevent spilling into the sewage system and waterways.		
	Other measures:	-		
7.1.2.	Advice on general occupational hygiene:			
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.			
7.2.	Conditions for safe storage, including any inco	ompatibilities		
	conditions:	Minimize dust formation. Avoid breathing in dust. Avoid contact with skin, eyes, and clothes. Keep in tightly closed containers.		
	Containers materials:	Manufacturer's original packaging.		



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	Requirements for storage rooms and vessels:	Keep in a tightly closed container. Keep in cool, dry and well ventilated space away from non-compatible substances.		
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.		
	Further information on storage conditions:	No information available.		
7.3.	Specific end use(s)			
	Recommendations:	-		
	Industrial sector specific solutions:	-		

SECTION 8. Ex	SECTION 8. Exposure controls/personal protection					
8.1. Cont	rol parameters					
Substance		CAS No	values/s	nal exposure limit hort term values	Biological limit values	
			ppm	mg/m³		
-	-		-	-	-	
Does not conta	ain substances re	gulated by the profe	essional exposu	ıre limit values.		
Substance name:	-					
EC No:	- CAS No: -					
DNEL						
			Industrial			
Route of exposure:		Acute fect local	Acute effect systemic	Chronic effect local	Chronic effect systemic	
Oral	-		-	-	-	
Inhalation	-		-	-	-	
Dermal	-		-	-	-	
Critical physica	l parameters: so	ubility, flammability,	corrosivity:			
			Consumer			
Route of Acute exposure: effect local			Acute effect systemic	Chronic effect local	Chronic effect systemic	
Oral	-		-	-	-	
Inhalation	-		-	-	-	
Dermal	Dermal					
PNEC						
Environmental	protection targe	t	PNEC			
<u> </u>						



Fresh water

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No information available

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Freshwater sediments		No information available			
Marine	water	No informatio	n available		
Marine s	sediments	No informatio	n available		
Food ch	ain	No informatio	No information available		
Microor	ganisms in sewage treatment	No informatio	n available		
Soil (agr	ricultural)	No informatio	n available		
Air		No informatio	n available		
8.2.	Exposure controls				
8.2.1.	Appropriate engineering controls				
	Substance/mixture related measures to during identified uses:	prevent exposure	Use personal protective equipment. Do not eat, drink or smoke in the workspace.		
	Structural measures to prevent exposure	Structural measures to prevent exposure:			
	Organisational measures to prevent exposure:		Organization of work in order to reduce other worker's influence during work process.		
	Technical measures for preventing expo	chnical measures for preventing exposure:			
8.2.2.	Personal protection equipment				
8.2.2.1.	Eye and face protection:	Safety glasses visor (EN 166).	that stick to face (preventing splashing) or		
8.2.2.2.	Skin protection				
	Hand protection:	The protective gloves to be used must comply specifications of EC Directive 89/686/EEC and the standard EN374 full contact: Gloves material: Nitrile rubber Glove thickness: 0.11 mm Break through time:> 480 min			
		splash contact			
			Gloves material: Nitrile rubber		
		Glove thickness: 0.11 mm Break through time:> 480 min			
	Other skin protection:	In normal circu footwear, such	umstances use cotton clothes and adequate as rubber boots or shoes that cover the case of spillage risk use clothes made of		



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		impermeable material suitable for protection against liquid chemicals (Viton, PVC himex - HRN EN 465) and footwear made of the same material.			
8.2.2.3.	Respiratory protection:	Required when dust are generated. Recommended filter type: Filter P 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances.			
8.2.2.4.	Thermal hazards:	-			
8.2.3.	Environmental exposure controls				
	Substance/mixture related measures to prevent exposure:	See Section 6			
	Structural measures to prevent exposure:	Use modern equipment.			
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.			
	Technical measures for preventing exposure:	See Section 6			

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



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	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:	No information available		
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).		
10.3.	Possibility of hazardous reactions:	Strong oxidizing agents		
10.4.	Conditions to avoid:	No information available		
10.5.	Incompatible materials:	No information available		
10.6.	Hazardous decomposition products:	No information available		

SECTION 11.	Toxicological informati	on				
11.1. Infor	mation on toxicological	effects				
Acut	e toxicity:					
Route of exposure:	Method	Sp	ecies	Dose LD ₅₀ /LC ₅₀	Exposure period	Result
Oral exposure:	No information available	No informati	on available	No information available	-	-
Skin contact:	No information available	No informati	No information available No in available		-	-
Inhaling:	No information available	No informati	No information available No ava		-	-
Spec	ific target organ toxicity	– single expos	ure (STOT SE):			
	Specific effe	cts	Target organ		١	lote
Oral exposure:	No information availab	ole	No information available		-	
Skin contact:	No information availab	le	No information available		-	
Inhaling:	No information availab	le	No information available		-	
Aspi	ration hazard:	No in	formation avail	able		
Irrita	tion and corrosion					
	Exposur	e time	Species	Evaluation	Method	Note



No

No

information

available

No

No

available

Subchronic

Chronic oral

inhalation

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				1	1		
Skin corrosion/irritation:		No information	available	No information available	-	No informati on available	No information available
Serious eye damage/irritation No informatio			available	No information available	-	No informati on available	No information available
Sensi	tization						
Skin contact:	No	information av	ailable				
Inhaling:	No	information av	ailable				
	i						
Symp	toms rela	ated to the phys	sical, chemical	and toxicolog	gical characteristic	S	
Oral exposure:	No	information av	ailable				
Skin contact:	No	information av	ailable				
Inhaling:	No	information av	ailable				
Eye contact:	No	information av	ailable				
;							
Repea	ated dose	e toxicity (subac	cute, subchron	ic, chronic)	:	:	:
	Do	se Exposu	re time	Species	Method	Evaluation	Note
Subacute oral	No informa availab	availah	information le	No information available	No informat available	tion -	-
Subacute dermal	No informa availab	: avallan	information le	No information available	No informat available	tion -	-
Subacute inhaling toxicity	No informa availab	availah	information le	No information available	No informat available	tion -	-
Subchronic oral	No informa availab	i availah	information le	No information available	No informat available	tion -	-
Subchronic dermal toxicity	No informa availab	availah	information le	No information available	No informat	tion -	-

No

No

information

available

information

information

No information

No information

available



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	information available	available	information available	available			
Chronic dermal toxicity	No information available	No information available	No information available	No information available	-	-	
Chronic inhalation	No information available	No information available	No information available	No information available	-	-	
Space	ific target organ	toxicity – repeated exp	oosuro (STOT PI	<u></u>			
эрсс	me target organ	Specific ef		Target organ	No	ote	
Subacute oral		No information availa		No information available	-		
Subacute derm	nal	No information availa	able	No information available	_		
Subacute inhal	ing toxicity	No information availa	able	No information available	-		
Subchronic ora	al	No information availa	able	No information available	-		
Subchronic dermal toxicity		No information availa	able	No information available	-		
Subchronic inh	alation	No information availa	able	No information available	_		
Chronic oral		No information availa	able	No information available	_		
Chronic derma	l toxicity	No information availa	able	No information available	_		
Chronic inhala	tion	No information availa	able	No information available	_		
		genicity, mutagenicity,	reproductive to	<u> </u>			
Carcinogenicity i			No information				
Mutagenicity in	TI-VILI U.		No information				
Genotoxicity:			No information				
Mutagenicity in-vivo:							
Germ cell mutagenicity: Reproductive toxicity:			No information available No information available				



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

12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure period	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	-	-
Microorganisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure period	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	_	_
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	-	_
Microorganisms	-	-	-	-	-	-

12.2.	Persi	Persistence and degradability								
	Abio	abiotic degradation								
		Degradation half-lives	Method	Evaluation	Note					
Marine	water	No information available	No information available	-	-					



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Fresh water	No	information	availab	le		No informat	ion	ı available	-	-
Air	No	information	availab	le		No informat	ion	ı available	-	_
Soil	ł	information				No informat			-	-
1										
Biod	egrad	dation							1	
% Degradation		Tir	ne (days	s)		Method		Evaluation	N	ote
No information available	No	information	n availab	le		No information available		No information available	-	
12.3. Bioa	ccum	ulative pote	ntial							
		coefficient: r		ol/wat	er (log k	(ow):				
Value Concentratio		рН		°C	Method		Evaluation		Note	
No information available		ormation ilable	-		_	No informatior available	1	No information available	No inform	nation
	oncei	ntration fact							_	_
Value			ecies			Method		Evaluation		lote
No informatio available	n	No inform available	ation		No infavailat	ormation ble		o information vailable	No informa available	ation
Chro	nic e	cotoxicity								
i	alue	•	Dose	:	posure eriod	Species		Method	Evaluation	Note
Chronic toxicit	ty on	fish	LC ₅₀		rmation lable	No information available		-	-	-
Chronic toxicit (Daphnia)	y on	crustacea	EC ₅₀		rmation lable	No information available		-	-	-



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12.4.	Mobi	lity in so	oil				
	Know	n or pre	dicted distribu	tion in environn	nental compartn	nents:	
	No in	ıformatio	on available				
	Surfa	ce tensio	on:				
	Vá	alue	c	C	Concentratio n	Method	Note
	No information No informati available		on available	No information available	No information available	-	
	Adso	rption /	desorption				
Transpo	ort	rt A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-wa	water No information available		No information available	No information available	No information available	-	
Water-a	air	No info	ormation le	No information available	No information available	No information available	-
Soil-air		No info	ormation le	No information available	No information available	No information available	-
12 5	Dogul	to of DD	T and vPvB asse	occur on t			
12.5.			on available	essment			
	INO III	normatic	on avallable				
12.6.	Endo	crina dis	rupting proper	tios			
12.0.					mnonents consid	dered to have endo	ocrine disrupting propert
					·•		17/2100 or Commission
	i	_		levels of 0.1%	_		
12.7.	Othe	r adverse	e effects				
	No in	formation	on available				

SECTION 13. Disposal considerations

13.1. Waste treatment methods



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13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport information	
Transporting/shipment by road	(ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by rail (I	RID)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Inland waterway transport (ADN	N)
UN number:	Not subject to transport regulations.



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UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA	n-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Further information: -	

SECTIO	ECTION 15. Regulatory information			
15.1.	Safety, health and	environmental regulations/legislation specific for the substance or mixture		
	EU regulations	EU regulations		
	Authorization and	or restrictions of use		
	Authorizations: -			
	Restrictions: -			
	Other E 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 793/93 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		



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		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 guideline)	g 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Transport of Hazardous Substances Act
15.2.	Chemical safety asses	sment
	None	

SECTIO	ON 16. 0	Other information		
16.1.	Indic	ation of changes:	-	
16.2.	Abbr	eviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative	
16.3.	Key literature references and source of data:		-	
16.4.	Relevant H statements (number and full text)		t)	
	H:	315 319 335	Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.	
16.5.	Train	ing advice:	-	
16.6.	Furth	er information:	** "X" in the product code marks different volumes	



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(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
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