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Trading name:	ORANGE G, C.I. 16230						
Product code:	OG-P-X**	Revision date:	21 Dec 2022	Version:	3		

SECTI	ON 1 Identification of the sub	stance	e/mixture and of the company/undertaking		
1.1.	Product identifier				
	Substance name:	ORAI	ANGE G, C.I. 16230		
	EC No:	217-7	-705-6		
	Synonyms:	Acid	d Orange 10, Acid Fast Orange G		
	Product code:	OG-F	-P-X**		
	REACH registration number:	-			
	CAS No:	1936	6-15-8		
	Index no.:	-			
1.2.	Relevant identified uses of the substance or mixture and uses advised against				
	Uses:		For staining keratin according to Papanicolaou, hematoxylin counterstain.		
	Uses advised against:		Only the identified uses are advised.		
	Reason why uses advised against:		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	v data sheet		
	Supplier:	Bi	BioGnost Ltd.		
	Address: N		Medjugorska 59, Zagreb		
	Telephone number:	+3	+385 1 2409997		
	Fax no.:	+3	+385 1 2404039		
	e-mail of competent person:	<u>m</u>	msds@biognost.hr		
	National contact person: -		-		
1.4.	Emergency telephone numbe	r			
	National Protection and Resc Directorate:	ue	112		
	Medical information:		+385 1 2348 342		
	Other information:		-		

SECTIO	ON 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*:			
	Not identified as hazardous substances	-			
2.1.2.	Additional information				
	-				



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*For fu	ull text of Hazard- and EU Hazard-	statements: see Section 16		
2.2.	Label elements			
	Product identification:	ORANGE G, C.I. 16230		
	Identification number:	-		
	Authorisation number:	-		
	Hazard pictograms:	-		
	Signal word:	-		
	Hazard statements:	-		
	Precautionary statements:	-		
	Further information:	-		
2.3.	Other hazards			
	Endocrine Disrupting Propert	ies:		
	No known endocrine disrupting	No known endocrine disrupting properties		
	Results of PBT and vPvB assessment : According to the results of its assessment, this substance is not a PBT or a vPvB.			

SECTION 3. Composition/information on ingredients						
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)		
1936-15-8	217-705-6	-	Disodium 7-hydroxy-8- phenylazonaphthalene-1,3-disulphonate	90-100 %		

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 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	-



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4.2.	Most important symptoms and effects, both acute and delayed					
	Following inhalation: Harmful if inhaled.					
	After skin contact:	Harmful in contact with skin.				
	Following eye contact:	Risk of serious damage to eyes.				
	Following ingestion:	Harmful if swallowed.				
4.3.	Indication of any immediate medical attention and special treatment needed					
	-					

SECTIC	N 5. Firefighting measures		
5.1.	Extinguishing media		
	Suitable extinguishing media: Water, foam, dry powder, CO ₂		
	Unsuitable extinguishing media: -		
5.2.	Special hazards arising from the substance or mixture		
	Hazardous combustion products: no information available		
5.3.	Advice for firefighters		
	Use a self-contained open-circuit 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 extinguishing fire does not contaminate water surface or underground waters system.		

SECTIC	ON 6. Accidental release	e measures			
6.1.	Personal precautions,	orotective e	quipment and emergency procedures		
6.1.1.	For non-emergency pe	ersonnel			
	Protective equipment:		Use personal protective equipment (see Section 8).		
	Accident prevention methods: Avoid breathing in dust. Avoid touching the substance. Secure proper ventilation.				
	Emergency procedures: Leave the hazardous area, take notice of the emergency procedures.				
6.1.2.	For emergency responders:				
	-				
6.2.	Environmental precaut	ions:			
	Do not allow the prod	uct enter dr	ainage.		
6.3.	Methods and material 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 v	waste material in tightly closed impermeable containers. Store the		



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		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 se	Reference to other sections							
	Indications about waste treatment, see Section 13.								

SECTIC	DN 7. Handling and storage								
7.1.	Precautions for safe handling								
7.1.1.	Protection measures								
	Measures to prevent fire:	Keep away from sources of ignition and heat. Do not use sparkling tools.							
	Measures to prevent aerosol and dust generation	on: 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. The	noroughly wash hands after work and before eating.							
7.2.	Conditions for safe storage, including any incon	npatibilities							
	Technical measures and storage conditions:	Minimize dust formation. Avoid breathing in dust. Avoid contact with skin, eyes, and clothes. Keep in tightly closed containers.							
	Containers materials:	Manufacturer's original packaging.							
	Requirements for storage rooms and vessels:	Keep in a tightly closed container. Keep in cool, dry and well ventilated space away from non-compatible substances.							
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.							
	Further information on storage conditions:	No information available.							
7.3.	Specific end use(s)								
	Recommendations: -								
	Industrial sector specific solutions: -								

SECTIC	SECTION 8. Exposure controls/personal protection											
8.1.	Control parameters	Control parameters										
Substance CAS No Occupational exposure Biological limit values												



Page 5 of 16 Trading name: **ORANGE G, C.I. 16230** Product code: OG-P-X** Revision date: 21 Dec 2022 Version: 3 limit values/short term values mg/m³ ppm _ _ _ Does not contain substances regulated by the professional exposure limit values. Substance name: EC No: CAS No: _ _ DNEL Industrial Acute Chronic Chronic **Route of** Acute exposure: effect local effect systemic effect local effect systemic Oral _ _ _ _ Inhalation Dermal _ _ _ Critical physical parameters: solubility, flammability, corrosivity: Consumer Acute Acute Chronic Chronic **Route of** exposure: effect local effect systemic effect local effect systemic _ _ _ _ Oral ---_ Inhalation _ _ Dermal **PNEC** Environmental protection target **PNEC** No information available Fresh water No information available Freshwater sediments Marine water No information available Marine sediments No information available Food chain No information available Microorganisms in sewage treatment No information available Soil (agricultural) No information available Air No information available 8.2. **Exposure** controls 8.2.1. Appropriate engineering controls



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Trading name: Product code:			0	RANG	E G, C.I. 16230	Fage 0	-				
<u> </u>		OG-P-X**	Revision		21 Dec 2022	Version:	3				
		ce/mixture related mea e during identified uses	•		personal protective moke in the workspa	• •	eat, drink				
	Structur	al measures to prevent	exposure:	No	information available	e					
		ational measures to pre			anization of work in ker's influence durin		ner				
	Technica	al measures for prevent	ing exposure:	оре	hnical measures and erations should be gir sonal protective equi	ven priority over the					
8.2.2.	Persona	protection equipment		i							
8.2.2.1.	Eye and	face protection:	Safety glasse 166).	es that s	tick to face (prevent	ing splashing) or vis	or (EN				
8.2.2.2.	Skin protection										
	Hand pr	otection:		Gloves Gloves Glove t Break t ct: Gloves Glove t	es to be used must of 86/EEC and the relat material: Nitrile rub thickness: 0.11 mm through time:> 480 r material: Nitrile rub thickness: 0.11 mm	ed standard EN374 ber min ber					
	Other sk	in protection:	In normal circumstances use cotton clothes and adequate footwear, such as rubber boots or shoes that cover the entire foot. In case of spillage risk use clothes made of impermeable material suitable for protection against liquid chemicals (Viton, PVC himex - HRN EN 465) and footwear made of the same material.								
8.2.2.3.	Respirat	ory protection:	•	N 3181)	are generated. Recc) for solid and liquid						
8.2.2.4.	Thermal	hazards:	-								
8.2.3.	Environ	mental exposure contro	ls								
		ce/mixture related mea exposure:	sures to See	See Section 6							
		Structural measures to prevent exposure:			n equipment.						
	0	Organisational measures to prevent exposure:			Adapt the work process to the required working conditions of the workplace.						
	Technica exposur	al measures for prevent e:	ing See	Section	6						



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1.	Information on basic physical and che	mical properties	
		Value	Method
	Physical state:	powder	No information available
	Colour:	orange yellow	No information available
	Odour/odour threshold:	odourless/no information available	No information available
	Melting point / freezing point:	141 °C	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

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							



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SECTION 11. To	xicol	ogical information	on								
11.1. Informa	ition o	on toxicological e	ffects								
Acute to	oxicity	<i>:</i> :									
Route of exposure:	Method Spec		Species		Do	ose LD ₅₀ /LC ₅₀	Ехро	osure peri	od	Result	
Oral exposure:	No ava	information ilable	No availa	inform able		No ava	information ilable	No availab	inform le	ation	-
Skin contact:	No ava	information ilable	No availa	inform able			information ilable	No availab	inform le	ation	-
Inhaling:	No ava	information ilable	No availa	inform able			information ilable	No availab	inform le	ation	-
Specific	targe	et organ toxicity –	- sinale	e exposu	ıre (STO	T SI	<u>=):</u>				
		Specific eff					arget organ			Not	e
Oral exposure:	No	information avai			No info		ation available	9	-		
Skin contact:	No	information avai	lable		No infe	orm	ation available)	-		
Inhaling:	No	information avai	lable		No information available -						
Aspirati				No in	formatio	on a	vailable				
Irritatio	n and	corrosion						1		1	
		Exposure tim		•	ecies		Evaluation	Me	thod		Note
Skin corrosion/irritati	on:	No informa available	ation No infor available				-	No information available		No availa	information able
Serious eye damage/irritatio	n	No informa available	ation	No in availab	formatio le	on	-	No informatior available		No availa	information able
Sensitiz	ation										
Skin contact:	N	lo information av	ailable	è.							
Inhaling:	N	lo information av	ailable	<u>)</u>							
		lated to the phys			and toxi	icolo	ogical characte	eristics			
Oral exposure:		lo information av									
Skin contact:		lo information av									
Inhaling:		lo information av									
Eye contact:	N	lo information av	ailable	د د							



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Repea	ted dose toxic	ity (sul	pacute, subchror	nic, chro	onic)	:	1	1
	Dose		Exposure time	Specie	es	Method	Evaluation	Note
Subacute oral	No inform available	ation	No information available	No inforn availa		No information available	No information available	-
Subacute dermal	No inform available	ation	ation No information available		nation ble	No information available	No information available	-
Subacute inhaling toxicity	No inform available	ation	No information available	No inforn availa		No information available	No information available	-
Subchronic oral	No inform available	ation	No information available	No inforn availa		No information available	No information available	-
Subchronic dermal toxicity	No inform available	ation	No information available	No information available		No information available	No information available	-
Subchronic inhalation	No inform available	ation	No information available	No inforn availa		No information available	No information available	-
Chronic oral	No inform available	ation	information		nation ble	No information available	No information available	-
Chronic dermal toxicity	No inform available	ation	No No information informat available available			No information available	No information available	-
Chronic inhalation	No inform available	ation	No information available	No informatior available		No information available	No information available	-
Specifi	ic target orgar	n toxici	ty – repeated ex	·				NL /
Subacute oral		No in	Specific effects formation availa			arget organ rmation availat		Note
Subacute derm	al		formation availa			rmation availat		
Subacute inhali			formation availa			rmation availat		
<u> </u>			formation availa			rmation availat		
Subchronic der			formation availa			rmation availab		
Subchronic inha	-		formation availa		No info	rmation availat	ole -	
Chronic oral		No in	formation availa	ble	No info	rmation availab	ole -	
Chronic dermal	toxicity	No in	formation availa	ble	No info	rmation availab	ole -	



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						,	,		
Chronic	inhalation	No inform	ation avai	ilable	No ir	nformation available -			
	CMR effec	ts (carcinogenicity, m	utagenici	ty, reprodu	uctive	toxicity)			
Carcino	genicity:		No info	ormation av	vailab	ole			
Mutage	nicity <i>in-vit</i>	ro:	No info	ormation av	vailab	ole			
Genoto	xicity:		No info	ormation av	vailab	ole			
Mutage	nicity <i>in-viv</i>	<i>'</i> 0:	No info	ormation av	vailab	ole			
Germ ce	ell mutagen	icity:	No info	ormation av	vailab	ole			
Reprod	uctive toxici	ty:	No information available						
	Summary properties	of evaluation of :	the CMF	IR No information available					
11.2.	Informatio	on 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 info	rmations:							
	-								

SECTION 12. Ecologi	SECTION 12. Ecological information							
12.1. Toxicity								
Acute (short-term) toxicity	Dose	Exposure period	Species	Method	Evaluation	Note		
Fish	LC ₅₀	96 hours	No information available	No information available	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	-		
Microorganisms	-	-	-	-	-	-		



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		1				
Fish LC	C ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea: EC	C ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	-50	72 hours	No information available	No information available	No information available	-
Microorganisms -		-	-	-	-	-

Abiot	ic 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	-

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

12.3. Bioaccumulative poten	tia
-----------------------------	-----

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

Value	Concentration	рН	°C	Method	Evaluation	Note
No informatio n available	No information available	-	-	No information available	No information available	No information available
Bio	concentration factor (BC					



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Tradia					~	DANCE	<u> </u>	6220		1	Page 12 of	10
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Produc	t code:	00	OG-P-X**		Revision date: 21 Dec		2022	2	V	ersion:	3	
V	alue		Species		Method		Evaluation			Note		
No info availabl	rmation e		information ailable		informa ailable	ation	No info availab		ion		nformation lable	
	Chronic	ecoto	kicity									
	Value		Dose	Exposur period		pecies	Metł	nod	Evaluati	on	Not	e
Chronic	Chronic toxicity on fish LC ₅₀		LC ₅₀	No informat on available	o formati n available		No inform on availal		No information available		n -	
Chronic toxicity on crustacea (Daphnia)		EC ₅₀	No informati on available		rmation lable	No inform on availal		No information available		-		
12.4.	Mobility	y in soil										
	Known	or pred	licted distributi	ion in envii	ronment	al compa	rtments:					
	No info	rmatio	n available									
	Surface	tensior	ion:									
	Valu	ie	°C	Concentration No information available						Note		
	No informa availabl		No information available					-				
	Adsorpt	tion / d	esorption									
Transpc	•	A/D c	oefficient s constant	log K	ow	Evaporat	vaporation rate		Method		Not	e
Soil-wat	ter ava	o ailable	information	No informati available	on	No information available			informati lable	on	-	
Water-a	air No ava	o ailable	information	No informati available	on	No info available			informati lable	on	-	
Soil-air	No ava	o ailable	information	No informati	on	No info available			informati lable	ion	-	



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	available							
12.5.	Results of PBT and vPvB assessment							
	No information available							
12.6.	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.							
12.7.	Other adverse effects							
	No information available							

SECTIO	N 13. Disposal considerations
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
12 1 2	
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.
1245	
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.				



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				·			
UN proper shipping name:		-					
Transport hazard class(es):		-					
Packing group:		-					
Environmental hazard(s):		-					
Special precautions for user:		-					
Transporti	ng/shipment by rail (RI	D)					
UN number:		Not subject to transport regulations.					
UN proper shipping	g name:	-					
Transport hazard cl	ass(es):	-					
Packing group:		-					
Environmental haza	ard(s):	-					
Special precautions	for user:	-					
Inland wat	erway transport (ADN)						
UN number:		Not	subject to transpo	ort regulations.			
UN proper shipping	g name:	-					
Transport hazard cl	ass(es):	-					
Packing group:		-					
Environmental haza	ard(s):	-					
Special precautions	for user:	-					
Transporti	ng/shipment by sea (IN	1DG)					
UN number:		Not	subject to transpo	ort regulations.			
UN proper shipping name:		-					
Transport hazard class(es):		-					
Packing group:		-					
Environmental haza	ard(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-DGR)							
UN number:		Not	subject to transpo	ort regulations.			
UN proper shipping name:		-					
Transport hazard class(es):		-					
Packing group:		-					
Environmental hazard(s):		-					
Special precautions for user:		-					



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

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Further information:

SECTIO	ON 15. Regulatory informa	ation				
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 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 dangerous substances, mixtures and articles (Annex XVII); 				
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC- guideline)					
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Transport of Hazardous Substances Act				
15.2.	Chemical safety assessment					
	None					

SECTIO	SECTION 16. Other information				
16.1.	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 			



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Trading name:		ORANGE G, C.I. 16230						
Product code: OG-P-X**			Revision date:	21 Dec 2022	Version:	3		
		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: PBT: vPvB:	Persistent, Bioaccu				
16.3.	Key literature references and source of data:		-					
16.4. Relevant H statements (number		r and f	ull text)					
	H: -		-					
16.5.	Training a	dvice:	-					
16.6.	of t Further information: We wit		** "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.				mply	

ANNEX:	
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Exposure scenario resulting to Chemical safety assessment