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Trading name:	ORCEIN, C.I. (ed. 1) 1242				
Product code:	ORC-P-X**	Revision date:	21 Dec 2022	Version:	4

1.1.	Product identifier			
	Substance name:	ORCEIN, C.I. (ed. 1) 1242		
	EC No:	215-750-6		
	Synonyms:	Natural Re	d 28, Orcein Synthetic	
	Catalogue number:	ORC-P-X*		
	REACH registration number:	-		
	CAS No:	1400-62-0		
	Index no.:	-		
1.2.	Relevant identified uses of th	e substance	or mixture and uses advised against	
	Uses:		For staining elastic tissues and antigen of the hepatitis B virus.	
	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 s	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			
	National Protection and Resc Directorate:	ue	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					



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P280 Wear protective protection/face prote P302+P352 IF ON SI P305+P351+P338 several minutes. Rem Continue rinsing.			
Authorisation number: Hazard pictograms: GHS07 Signal word: Warning H315 Causes skin in H319 Causes seriou H335 May cause re P280 Wear protective protection/face protect	2		
Hazard pictograms: GHS07 Signal word: Warning H315 Causes skin in H319 Causes seriou H335 May cause re P280 Wear protection/face protectio			
GHS07 Signal word: Hazard statements: Hazard statements: Hazard statements: Hasard statements: Page 44 Page 44 Page 45 P			
Hazard statements: Hazard statements: Hasard statements: Hasard statements: Hasard statements: Hasard statements: Hasard statements: Hasard statements: Page 4 Pag			
Hazard statements: H319 Causes seriou H335 May cause re P280 Wear protective protection/face prote P302+P352 IF ON SI P305+P351+P338 several minutes. Rem Continue rinsing. P308 + P313 IF exp advice/attention.			
Precautionary statements: Precautionary statements: Precautionary statements: Precautionary statements: Precautionary statements: Precautionary statements: Protection/face prote Protection/face protection Protectio			
Further information: -	ploves/protective clothing/eye tion. N: Wash with plenty of water and soap. IF IN EYES: Rinse cautiously with water for we contact lenses, if present and easy to do.		
.3. Other hazards	Other hazards		

SECTION 3. Composition/information on ingredients						
CAS No	EC No:	Index no.	Identification name	Weight % content (or range)		
1400-62-0	215-750-6	-	Orcein	90-100%		
SECTION	SECTION 4. First aid measures					
4.1.	Description of first aid measures					
	General notes:		-			



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	Following inhalation: Following skin contact: Following eye contact: Following ingestion: Self-protection of the first aider		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.	
			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.	
			Rinse out with plenty of water with the eyelid held wide oper using clean fingers. If the symptoms remain, immediately call a physician. 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.	
4.2.	Most important symptoms	and effects, be	oth acute and delayed	
	Following inhalation:	Harmful if	inhaled.	
	After skin contact:	Harmful ir	n contact with skin.	
	Following eye contact:	Risk of ser	ious damage to eyes.	
	Following ingestion:	Harmful if	swallowed.	
4.3.	Indication of any immediat	ite medical attention 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 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.				

SECTIO	SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures		
6.1.1.	For non-emergency personnel		



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	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	duct 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 se	ections		
	Indications about waste treatment, see Section 13.			

SECTIO	N 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 gene	ration:	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	e. Thoro	ughly wash hands after work and before eating.
7.2.	Conditions for safe storage, including any in	ncompat	ibilities
	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. I	Exposure cont	rols/personal protec	ction		
8.1. Cor	ntrol parameter	S			
Sub	ostance	CAS No		exposure limit t term values	Biological limit values
			ppm	mg/m³	-
-		-	-	-	-
Does not con	tain substance	s regulated by the pro	ofessional exposure	limit values.	
Substance name:	-				
EC No:	-	CAS No: -			
DNEL					
			Industrial		
Route of		Acute	Acute	Chronic	Chronic
exposure:		effect local	effect systemic	effect local	effect systemic
Oral	-		-	-	-
Inhalation	-		-	-	-
Dermal	-		-	-	-
Critical physic	cal parameters:	solubility, flammabili	ty, corrosivity:		
			Consumer		
Route of		Acute	Acute	Chronic	Chronic
exposure:		effect local	effect systemic	effect local	effect systemic
Oral	-		-	-	-
Inhalation	-		-	-	-
Dermal	-		-	-	-
PNEC					
Environmenta	al protection ta	raet	PNEC		



Fresh water

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No information available

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		_		
Freshwa	ter sediments	No information available		
Marine	water	No information	available	
Marine s	sediments	No information	available	
Food ch	ain	No information available		
Microor	ganisms 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 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	: :	No information available	
	Organisational measures to prevent exp	osure:	Organization of work in order to reduce other worker's influence during work process.	
	Technical measures for preventing expo	sure:	Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.	
8.2.2.	Personal protection equipment			
8.2.2.1.	Eye and face protection:	Safety glasses the visor (EN 166).	nat stick to face (preventing splashing) or	
8.2.2.2.	Skin protection			
	Hand protection:	The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related 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 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		



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		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 chemical	al properties	
		Value	Method
	Physical state:	powder	No information available
	Colour:	orange brown	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
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information availabl
	Vapour pressure:	No information available	No information availabl



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	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:	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	

	rmation on toxicological	effects				
Acut	te toxicity:					
Route of exposure:	Method	S	pecies	Dose LD ₅₀ /LC ₅₀	Exposure period	Result
Oral exposure:	No information available	No informa	tion available	No information available	-	-
Skin contact:	No information available	No information available No information available		-	-	
Inhaling:	No information available	No informa	tion available	No information available	-	-
Spe	cific target organ toxicity	– single expo	sure (STOT SE):			
	Specific effec	ts	Targ	et organ	No	ote
Oral exposure:	No information availab	le	No information	n available	-	
Skin contact:	No information availab	le	No information	n available	-	
Skill Colliact.	NI = i = f = un= = ti = u = u = i = l= l=	le	No information	n available	-	
Inhaling:	No information availab					
	NO Information availab		3			



dermal

toxicity

Subchronic

inhalation

information

information

available

available

No

available

available

information

No

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Product code:	: ORC-F	P-X**	Revision date:	Revision date: 21 Dec 2022		: 4
					N	.
		Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irrita	tion:	information availabl	e No informat available	ion _	No information available	No information available
Serious eye damage/irritation		information availabl	e No informat available	ion _	No information available	No information available
Sensi	tization					
Skin contact:	No info	ormation available				
Inhaling:	No info	ormation available				
Symp	toms related	I to the physical, che	emical and toxicol	ogical characteristics		
Oral exposure:	No info	ormation available				
Skin contact:	No info	ormation available				
Inhaling:	No info	ormation available				
Eye contact:	No info	ormation available				
Repea	ated dose to	xicity (subacute, sub	chronic, chronic)		:	-
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No informatio available	n No informat available	tion No informat available	ion No information available	-	-
Subacute dermal	No informatio available	No informat available	tion No informat	ion No information available	_	-
Subacute inhaling toxicity	No informatio available	n No informat available	tion No informat available	ion No information available	_	-
Subchronic oral	No informatio available	No informat n available	tion No informat available	ion No information available	-	-
Subchronic dermal	No informatio	No informat	tion No informat	ion No information	_	_

available

available

No information

available

available

No information



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Chronic oral	No information available	No information available	No information available	No information 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	-	-	
Spec	ific target organ	toxicity – repeated ex	·				
		Specific 6	effects	Target organ		Note	
Subacute oral		No information ava	ilable	No information available	-		
Subacute dern	nal	No information ava	ilable	No information available	-		
Subacute inhaling toxicity		No information ava	ilable	No information available	-		
Subchronic oral No inform		No information ava	o information available		-		
Subchronic de	rmal toxicity	No information available		No information available	-		
Subchronic inh	nalation	No information ava	information available		-		
Chronic oral		No information ava	nformation available		_		
Chronic derma	l toxicity	No information ava	ilable	No information available	-		
Chronic inhala	tion	No information ava	ilable	No information available	-		
CNAD	offorto (sersio	anniaite, montananaiste	, woo wo directions to a	i cit. A			
		genicity, mutagenicity	No information				
Carcinogenicity			No information				
Mutagenicity <i>i</i> Genotoxicity:	11-VUI U.		No information				
Mutagenicity i	n-vivo		No information				
Germ cell mutagenicity:			No information available No information available				



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	Summary of evaluation of the CMR properties:	No information available
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 information:	
	-	

SECTION 12. Ecologi	cal informa	tion				
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	-	-	-	-	-	-



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	istence and degr	adability					
Abic	otic degradation	عاددا دروا	Para -		4 - 4	F l	NI-4-
		tion half			1ethod	Evaluation	Note
Marine water	No information			No information		-	-
Fresh water	No information			No information		-	-
Air	No information			No information		-	-
Soil	No information	n availabl	e	No information	n available	-	-
Biod	legradation						
% Degradation	Tir	ne (days)		Method	Evaluation	N	ote
No information available	No informatio	n availab	le	No information available	No information available	-	
	ccumulative pote		l/water (log	Kow):	Evaluation		Note
value	n	Pii		Method	Lvaidation		Note
No information available	No information available	-	-	No information available	No information available	n No inforr available	
Rioc	oncentration fac	tor (RCF)	1	<u> </u>		1	
Value		ecies	**************************************	Method	Evaluation	N	Note
No informatio available	-		No ir	nformation	No information available	No informavailable	
Chro	onic ecotoxicity						
V	alue	Dose	Exposure period	Species	Method	Evaluation	Note



12.6.

Endocrine disrupting properties

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				ORCEIN, C.I. (ed. 1) 1242			
ode:	ORC-P-X	**	Re	vision date: 21	1 Dec 2022	Vers	ion:	4
xicity on	fish	LC ₅₀	No informati on available	No information available	-	-	-	
xicity on	crustacea	EC ₅₀	No informati on available	No information available	-	-	-	
Mohility	in soil							
		distribut	ion in enviro	nmental compartm	nents:			
	·····•			· · · · · · · · · · · · · · · · · ·				
		°C		Concentration	Method		Note	
No nformati available	on No in	ormatio	n available	No information available	No information available	-		
	A/D coeffic	cient	log Kow	Evaporation	Method		Note	
No	informatio		No informati on available	No information available	No information available	-		
		n	No informati on available	No information available	No information available	-		
		n	No informati on available	No information available	No information available	-		
	xicity on Mobility Known o No inform Value No Information Adsorption No available	No information available No information No information available Adsorption / desorption / des	Mobility in soil Known or predicted distribut No information available Surface tension: Value No Information A/D coefficient Henry's constant No information available No information available No information available No information available	xicity on fish LC50	xicity on fish LC50	informati on available Coso Informati on available Coso Informati on available Coso Informati on available Coso Coso Concentration Coso Coso Concentration Coso Coso	xicity on fish LCso information available xicity on crustacea ECso information available To information in environmental compartments: Value	xicity on fish LC50



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	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

SECTION	I 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.	
12.1.2		
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:	
	-	

Transporting/shipment by road (ADR)		
Transporting/simplifient by road	I (ADN)	
UN number:	Not subject to transport regulations.	
UN proper shipping name:	-	
Transport hazard class(es):	-	
Packing group:	-	
Environmental hazard(s):	-	
Special precautions for user:	-	



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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)	
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 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/IAT	A-DGR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazard(s):	-
Special precautions for user:	-
Further information: -	

SECTION 15. Regulatory information			
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture		
	EU regulations		
	Authorization and/or restrictions of use		



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	Authorizations:	-	
	Restrictions:	-	
	Other EU regulations:	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC; Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work; Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; REACH Restrictions on the manufacturing, placing on the market and use of certain	
		dangerous substances, mixtures and articles (Annex XVII);	
	Information according 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 assessment		
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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 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			



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Trading name:	ORCEIN, C.I. (ed. 1) 1242				
Product code:	ORC-P-X**	Revision date:	21 Dec 2022	Version:	4

16.3.	Key literature references and source of data:		-
16.4.	Relev	ant H statements (number and full te	ext)
		315	Causes skin irritation.
	H:	319	Causes serious eye irritation.
		335	May cause respiratory irritation.
16.5.	Training advice:		-
			** "X" in the product code marks different volumes (different packagings of the product)
16.6.	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