

Trading name:	<b>ORCEIN, C.I. (ed. 1) 1242</b>		
Product code:	ORC-P-X**	Revision date:	31.07.2019. Version: 3


**SECTION 1. Identification of the substance/mixture and of the company/undertaking**

<b>1.1. Product identifier</b>	
Substance name:	ORCEIN, C.I. (ed. 1) 1242
EC No:	215-750-6
Synonyms:	Natural Red 28, Orcein Synthetic
Catalogue number:	ORC-P-X**
REACH registration number:	-
CAS No:	1400-62-0
Index no.:	-
<b>1.2. Relevant identified uses of the substance or mixture and uses advised against</b>	
Uses:	For microscopy.
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, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
<b>1.3. Details of the supplier of the safety data sheet</b>	
Supplier:	BioGnost Ltd.
Address:	Medjugorska 59, Zagreb
Telephone number:	+385 1 2409997
Fax no.:	+385 1 2404039
e-mail of competent person:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
National contact:	-
<b>1.4. Emergency telephone number</b>	
National Protection and Rescue Directorate:	112
Medical information:	+385 1 2348 342
Other information:	-

**SECTION 2. Hazards information**

<b>2.1. Classification of the substance or mixture</b>	
<b>2.1.1. Classification according to Regulation (EC) No 1272/2008 (CLP)</b>	
Hazard class and category code:	Hazard statements*:
Skin Irrit. 2	H315
Eye Irrit. 2	H319
STOT-SE 3	H335
<b>2.1.2. Additional information</b>	
-	
*For full text of Hazard- and EU Hazard-statements: see Section 16	
<b>2.2. Label elements</b>	

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Product identification:	ORCEIN, C.I. (ed. 1) 1242
Identification number:	-
Authorization no.:	-
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. P501 Dispose of contents/container to the container approved for waste disposal.
Supplemental hazard information (EU):	-
2.3. 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 4. First aid measures	
4.1.	Description of first aid measures
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
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 copious amounts of water for at least 15 minutes. Seek medical assistance if

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		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. Seek medical attention in case of irritation or other symptoms.
	Self-protection of the first aider:	-
<b>4.2.</b>	<b>Most important symptoms and effects, both acute and delayed</b>	
	Following inhalation:	Harmful if swallowed.
	Following skin contact:	Harmful by inhalation and in contact with skin.
	Following eye contact:	Risk of serious damage to eyes.
	Following ingestion:	Harmful if swallowed.
<b>4.3.</b>	<b>Indication of any immediate medical attention and special treatment needed</b>	
	-	

<b>SECTION 5. Firefighting measures</b>		
<b>5.1.</b>	<b>Extinguishing media</b>	
	Suitable extinguishing media:	water, foam, dry powder, CO <sub>2</sub>
	Unsuitable extinguishing media:	-
<b>5.2.</b>	<b>Special hazards arising from the substance or mixture</b>	
	Hazardous combustion products:	Certain substances may occur in case of fire: nitrogen oxides, sulfur oxides.
<b>5.3.</b>	<b>Advice for firefighters</b>	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
<b>5.4.</b>	<b>Additional information</b>	
	Make sure the water used for extinguishing fire does not contaminate water surface or groundwaters.	

<b>SECTION 6. Accidental release measures</b>		
<b>6.1.</b>	<b>Personal precautions, protective equipment and emergency procedures</b>	
<b>6.1.1.</b>	<b>For non-emergency personnel</b>	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Avoid inhaling dust. Avoid contact with the substance. Secure proper ventilation.
	Emergency procedures:	Leave the hazardous area, pay attention to emergency procedures, consult with expert.
<b>6.1.2.</b>	<b>For emergency responders:</b>	
	-	
<b>6.2.</b>	<b>Environmental precautions:</b>	

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	The product must not enter sewers.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	For creating barriers, covering and sealing:	Cap the drains. Collect, bundle and pump out everything that got spilled. Pay attention to the possible material restrictions (see Sections 7 and 10). Collect in dry form.
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 involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	For indications of waste processing see Section 13.	

<b>SECTION 7. Handling and storage</b>		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	-
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Minimize dust formation. Avoid inhaling vapor, dust, mist or gas. Avoid contact with skin, eyes and clothes. Keep in tightly closed container. Avoid swallowing and breathing.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep container tightly closed. Keep in cool, dry and well-ventilated space, away from incompatible 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:	-

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**SECTION 8. Exposure controls/personal protection**

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
-	-	-	-	-

Substance name: -

EC No: - CAS No: -

**DNEL**

**Industrial**

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity:

**Consumer**

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

**PNEC**

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

8.2. Exposure controls

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8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified 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 prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Use with appropriate ventilation.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	In case of coming into thorough contact, use butyl rubber gloves (0.4 mm thick). In case of contact with drops, use polychlorene gloves (0.1 mm thick).
	Other skin protection:	During everyday work use cotton clothing and suitable footwear, such as rubber boots or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values, use full gas mask equipped with brown filter A.
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 to prevent exposure:	See Section 6

**SECTION 9. Physical and chemical properties**

9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	powder	No information available
	Color:	orange brown	No information available
	Odor:	No information available	No information available
	Odor threshold:	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing	No information available	No information available

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	point;		
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapor pressure:	No information available	No information available
	Vapor density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2.	Other information		
	-		

<b>SECTION 10. Stability and reactivity</b>		
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:	No information available
10.4.	Conditions to avoid:	Strong heating.
10.5.	Incompatible materials:	Strong oxidizers and reducing agents.
10.6.	Hazardous decomposition products:	No information available

<b>SECTION 11. Toxicological information</b>					
11.1. Information on toxicological effects					
Acute toxicity:					
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub>	Exposure time	Results

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Oral exposure:	No information available	No information available	No information available	No information available	-
Dermal exposure:	No information available	No information available	No information available	No information available	-
Inhalation exposure:	No information available	No information available	No information available	No information available	-

**Specific target organ toxicity – single exposure (STOT SE):**

	Specific effects	Target organ	Note
Oral exposure:	No information available	No information available	-
Dermal exposure:	No information available	No information available	-
Inhalation exposure:	No information available	No information available	-

**Aspiration hazard:** No information available

**Irritation and corrosion**

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	No information available	No information available	-	No information available	No information available
Serious eye damage/irritation	No information available	No information available	-	No information available	No information available

**Sensitization**

Dermal exposure:	No information available
Inhalation exposure:	No information available

**Symptoms related to the physical, chemical and toxicological characteristics**

Oral exposure:	Harmful if swallowed.
Dermal exposure:	Harmful by inhalation and in contact with skin.
Inhalation exposure:	Harmful if swallowed.
Eye exposure:	Risk of serious damage to eyes.



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Repeated dose toxicity (subacute, subchronic, chronic)						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	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	No information available	-

Specific target organ toxicity – repeated exposure (STOT RE):			
	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

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CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No information available
Mutagenicity <i>in-vitro</i> :	No information available
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	No information available
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No information available
Summary of evaluation of the CMR properties:	No information available
<b>11.2. Practical experiences:</b>	
Remarks relevant for classification:	No information available
Other remarks:	No information available
<b>11.3. General notes:</b>	
-	

<b>SECTION 12. Ecological information</b>						
<b>12.1. Toxicity</b>						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-

Trading name:	<b>ORCEIN, C.I. (ed. 1) 1242</b>				
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			available	available	available	
Algae/aquatic plants	IC <sub>50</sub>	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	-

**12.3. Bioaccumulative potential**

Partition coefficient: n-octanol/water (log Kow):						
Value	Concentration	pH	°C	Method	Evaluation	Note
No information available	No information available	-	-	No information available	No information available	No information available

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

**Chronic ecotoxicity**

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

**12.4. Mobility in soil**

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

Value	°C	Concentration	Method	Note
No information available	No information available	No information available	No information available	-

**Adsorption / desorption**

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-

**12.5. Results of PBT and vPvB assessment**

No information available

**12.6. Other adverse effects**

No information available

**SECTION 13. Disposal considerations**

**13.1. Waste treatment methods**

No information available

**13.1.1. Product/Packaging disposal:**

No information available

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	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: -

<b>SECTION 14 TRANSPORT INFORMATION</b>	
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 (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:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-

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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-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:	-

<b>SECTION 15. Regulatory information</b>	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -
Other EU regulations:	<p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19</p>

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	November 2008 on waste and repealing certain Directives
	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

<b>SECTION 16. Other information</b>											
16.1.	Indication of changes: -										
16.2.	Abbreviations and acronyms: <table border="0" style="width: 100%;"> <tr> <td style="width: 150px;">PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD<sub>50</sub></td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC<sub>50</sub></td> <td>Lethal concentration, 50%</td> </tr> <tr> <td>STOT-SE</td> <td>Specific target organ toxicity - single exposure</td> </tr> </table>	PBT	Stable, bioaccumulative and toxic	vPvB	Strongly stable and strongly bioaccumulative.	LD <sub>50</sub>	Lethal dose, 50%	LC <sub>50</sub>	Lethal concentration, 50%	STOT-SE	Specific target organ toxicity - single exposure
PBT	Stable, bioaccumulative and toxic										
vPvB	Strongly stable and strongly bioaccumulative.										
LD <sub>50</sub>	Lethal dose, 50%										
LC <sub>50</sub>	Lethal concentration, 50%										
STOT-SE	Specific target organ toxicity - single exposure										
16.3.	Key literature references and source of data: -										
16.4.	Relevant H statements (number and full text)										
	<table border="0" style="width: 100%;"> <tr> <td style="width: 150px;">H: H315</td> <td>Causes skin irritation.</td> </tr> <tr> <td>H: H319</td> <td>Causes serious eye irritation.</td> </tr> <tr> <td>H: H335</td> <td>May cause respiratory irritation.</td> </tr> </table>	H: H315	Causes skin irritation.	H: H319	Causes serious eye irritation.	H: H335	May cause respiratory irritation.				
H: H315	Causes skin irritation.										
H: H319	Causes serious eye irritation.										
H: H335	May cause respiratory irritation.										
16.5.	Training advice: -										
16.6.	Further information: <p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>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.</p>										

<b>ANNEX:</b>
<b>EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT</b>
-