

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

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

1.1.	Product identifier	
	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.:	-
1.2.	Relevant identified uses of the 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 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 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	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

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	

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

-

*For full text of Hazard- and EU Hazard-statements: see Section 16

2.2. Label elements

Product identification:	ORCEIN, C.I. (ed. 1) 1242
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

<p>Endocrine Disrupting Properties: No known endocrine disrupting properties</p> <p>Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.</p>

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

	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 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	
	-	

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.	

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

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

	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 precautions:	Do not allow the product enter drainage.
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 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	Indications about waste treatment, see Section 13.

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 generation:	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 incompatibilities	
	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	Keep in a tightly closed container. Keep in cool, dry and well

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

vessels:	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. Exposure controls/personal protection

8.1. Control parameters

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

Does not contain substances regulated by the professional exposure limit values.

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

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

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

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 for preventing exposure:	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 that stick to face (preventing splashing) or visor (EN 166).

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 material suitable for protection against liquid chemicals

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

		(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

SECTION 9. Physical and chemical properties

9.1.	Information on basic physical and chemical 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 available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available

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

	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
	-		

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 information						
11.1.	Information on toxicological effects					
	Acute toxicity:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀	Exposure period	Result	
Oral exposure:	No information available	No information available	No information available	-	-	
Skin contact:	No information available	No information available	No information available	-	-	
Inhaling:	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	-			
Skin contact:	No information available	No information available	-			
Inhaling:	No information available	No information available	-			
	Aspiration hazard:					
	No information available					

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

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						
Skin contact:	No information available					
Inhaling:	No information available					
Symptoms related to the physical, chemical and toxicological characteristics						
Oral exposure:	No information available					
Skin contact:	No information available					
Inhaling:	No information available					
Eye contact:	No information available					
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	-	-
Subacute dermal	No information available	No information available	No information available	No information available	-	-
Subacute inhaling toxicity	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	-	-
Subchronic dermal toxicity	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	-	-
Chronic oral	No	No information	No	No	-	-

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

	information available	available	information available	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	-	-

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 inhaling toxicity	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal toxicity	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal toxicity	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)

Carcinogenicity:	No information available
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Trading name:	ORCEIN, C.I. (ed. 1) 1242				
Product code:	ORC-P-X**	Revision date:	21 Dec 2022	Version:	4

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
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:	
-	

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	-	-
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	-	-

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

Crustacea:	EC ₅₀	48 hours	No information available	available No information available	-	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	-	-
Microorganisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	-	-
Fresh water	No information available	No information available	-	-
Air	No information available	No information available	-	-
Soil	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
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Trading name:	ORCEIN, C.I. (ed. 1) 1242				
Product code:	ORC-P-X**	Revision date:	21 Dec 2022	Version:	4

No information available	No information available	No information available	No information available	No information available

Chronic ecotoxicity						
Value	Dose	Exposure period	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	-	-	-
Chronic toxicity on crustacea (Daphnia)	EC ₅₀	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	No	No	No	-

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

	available	informati on available	information available	information 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			

SECTION 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
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:
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SECTION 14. Transport information	
	Transporting/shipment by road (ADR)

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

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:	-
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/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:	-

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

Further information:	-
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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	
	Authorizations:	-
	Restrictions:	-
	Other regulations:	<p>EU</p> <p>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;</p> <p>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;</p> <p>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;</p> <p>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;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	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	

SECTION 16. Other information

16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of</p>

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

		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)	
	315 H: 319 335	Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.
16.5.	Training advice:	-
16.6.	Further information:	** "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.

ANNEX:
Exposure scenario resulting to Chemical safety assessment
-