

Trading name:	<b>OSTEOSENS</b>			
Product code:	OS-OT-X**	Revision date:	28 May 2019	Version: 4


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

<b>1.1</b>	<b>Product identifier</b>	
	Trading name:	OSTEOSENS
	Chemical name:	-
	Catalogue number:	OS-OT-X**
<b>1.2</b>	<b>Relevant identified uses of the substance or mixture and uses advised against</b>	
	Uses:	Decalcifying solution for sensitive calcified tissue in histology.
	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</b>	<b>Details of the supplier of the safety data sheet</b>	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
<b>1.4</b>	<b>Emergency telephone number</b>	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

**SECTION 2. Hazards identification**

<b>2.1</b>	<b>Classification of the substance or mixture</b>	
<b>2.1.1</b>	<b>Classification according to Regulation (EC) No 1272/2008 (CLP)</b>	
	Hazard class and category code:	Hazard statements*:
	Eye irrit. 2	H319
<b>2.1.2.</b>	<b>Additional information</b>	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
<b>2.2</b>	<b>Label elements</b>	
	Product identification:	OSTEOSENS
	Identification number:	-
	Authorization number:	-

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Hazard pictograms:	
	GHS07
Signal word:	Warning
Hazard statements:	H319 Causes serious eye irritation.
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. 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.
Supplemental hazard information (EU):	-

2.3	Other hazards
	-

**SECTION 3. Composition/information on ingredients**

CAS/EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
60-00-4/ 200-449-4/ 607-429-00-8	-	≤ 20 %	EDTA	Eye Irrit. 2; H319
1310-73-2/ 215-185-5/ 011-002-00-6	-	< 5%	sodium hydroxide	Skin Corr. 1A; H314

**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. In case of difficult breathing, provide the afflicted person with oxygen.
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.

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	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Do not induce vomitig. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
<b>4.2</b>	<b>Most important symptoms and effects, both acute and delayed</b>	
	Following inhalation:	May cause respiratory irritation.
	Following skin contact:	Causes skin irritation.
	Following eye contact:	Causes serious eye irritation.
	Following ingestion:	Swallowing a small quantity of this material will result in serious health hazard.
<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:	Small fire - water spray, dry powder, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	No information available
<b>5.2</b>	<b>Special hazards arising from the substance or mixture</b>	
	Hazardous combustion products:	Build up of harmful fumes, nitrogen oxides.
<b>5.3</b>	<b>Advice for firefighters</b>	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
<b>5.4</b>	<b>Additional information</b>	
	Do not contaminate the environment with extinguishing media.	

<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:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
<b>6.1.2.</b>	<b>For emergency responders:</b>	

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	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. 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:	Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	-	

<b>SECTION 7. Handling and storage</b>		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms.
	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:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	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.

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Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
<b>7.3</b>	<b>Specific end use(s)</b>
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 <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	
Freshwater sediments	
Marine water	
Marine sediments	

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Food chain	
Microorganisms in sewage treatment	
Soil (agricultural)	
Air	

<b>8.2</b>	<b>Exposure controls</b>
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<b>8.2.1.</b>	<b>Appropriate engineering controls</b>
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	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.

<b>8.2.2.</b>	<b>Personal protection equipment</b>
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8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN374. Glove material: nitrile rubber Glove thickness: 0.70 mm Time until perforation: > 480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13688) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Suitable mask (EN 136) equipped with a "A" filter (EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available

<b>8.2.3.</b>	<b>Environmental exposure controls</b>
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	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.

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Technical measures to prevent exposure:	See Section 6
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**SECTION 9. Physical and chemical properties**

9.1	Information on basic physical and chemical properties		
		Value	Method
Physical state:		liquid	No information available
Colour:		colourless	No information available
Odour:		No information available	No information available
Odor threshold:		No information available	No information available
pH:		7.0 – 7.4	No information available
Melting point / freezing point;		No information available	No information available
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
Vapour pressure:		No information available	No information available
Vapour 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		
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**SECTION 10. Stability and reactivity**

10.1	Reactivity:	See subsections 10.3 through 10.5.
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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:	No information available
10.5	Incompatible materials:	No information available
10.6	Hazardous decomposition products:	Nitrogen oxides

<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> or ATE <sub>mix</sub>	Exposure time	Results
Oral:	-	rat (EDTA)	LD <sub>50</sub>	-	2000 mg/kg
Dermal:	-	-	-	-	-
Inhalation:	-	-	LC <sub>50</sub>	-	-
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
Aspiration hazard: No information available.					
Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	causes serious eye irritation
Sensitization					
Skin sensitization:	No information available				
Respiratory sensitization:	No information available				
Symptoms related to the physical, chemical and toxicological characteristics					
Oral exposure:	Damage to gastrointestinal tract, acid-basic balance disorders, damage to blood and kidneys.				



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Dermal exposure:	Irritating and corrosive effects for skin.
Inhalation exposure:	Irritating and corrosive effects for airways.
Eye exposure:	Danger of permanent eye damage.

Repeated dose toxicity (subacute, subchronic, chronic)						
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	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):						
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	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	-

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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	-

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</b>	<b>Practical experiences:</b>
	Classification observations: No information available
	Other observations: No information available
<b>11.3</b>	<b>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	-	-	-	-
Crustacea:	EC <sub>50</sub>	48 hours	-	-	-	-
Algae/aquatic plants	IC <sub>50</sub>	3 days	-	-	-	-
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	-

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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	-	-	-	-	-	-

**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	No information available

**12.3 Bioaccumulative potential**

Octanol-water partition coefficient (log K<sub>ow</sub>)

Value	Concentration	pH	°C	Method	Evaluation	Note
-	-	-	-	-	-	-

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

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Chronic ecotoxicity						
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 ( <i>Daphnia</i> )	EC <sub>50</sub>	No information available	No information available	No information available	No information available	-
<b>12.4 Mobility in soil</b>						
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	-
<b>12.5 Results of PBT and vPvB assessment</b>						
No information available						
<b>12.6 Other adverse effects</b>						
No information available						

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<b>SECTION 13. Disposal considerations</b>	
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:
	15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances
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.
13.1.6.	Relevant Community provisions:
	-

<b>SECTION 14 TRANSPORT INFORMATION</b>	
Transporting/shipment by road (ADR)	
UN number:	Not subject to marking regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	Not subject to marking regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-

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Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	Not subject to marking regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	Not subject to marking regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
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 marking regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
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: -

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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 November 2008 on waste and repealing certain Directives</p>
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
National legislation:	<p>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, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act</p>
15.2	Chemical safety assessment
	None

<b>SECTION 16. Other information</b>											
16.1	Indication of changes: -										
16.2	<table border="0"> <tr> <td>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>TCOJ</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%	TCOJ	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%										
TCOJ	Specific target organ toxicity - single exposure										
16.3.	Key literature references and source of data: -										
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)										
	<table border="0"> <tr> <td>Classification</td> <td>Classification procedure</td> </tr> <tr> <td>-</td> <td>-</td> </tr> </table>	Classification	Classification procedure	-	-						
Classification	Classification procedure										
-	-										
16.5.	Relevant H statements (number and full text)										
	<table border="0"> <tr> <td>H: H314</td> <td>Causes severe skin burns and eye damage.</td> </tr> <tr> <td>H319</td> <td>Causes serious eye irritation.</td> </tr> </table>	H: H314	Causes severe skin burns and eye damage.	H319	Causes serious eye irritation.						
H: H314	Causes severe skin burns and eye damage.										
H319	Causes serious eye irritation.										
16.6.	Training advice: -										

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16.7.	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>
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<b>ANNEX: Exposure scenario resulting to chemical safety assessment</b>
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