

Trade name:	REDUCING BUFFER, SOLUTION				
Product code:	RP-OT-X**	Date of compilation:	05 July 2019	Version:	3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	REDUCING BUFFER, SOLUTION
	Chemical name:	-
	Catalogue number:	RP-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Von Kossa kit.
	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 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
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone numbers	
	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 statement*:
	Skin Sens. 1	H317
	Resp. Sens. 1	H334
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	REDUCING BUFFER, SOLUTION
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	 
	GHS07 GHS08
Signal word:	Danger
Hazard statement:	H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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: Call a POISON CENTER or doctor.
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)
30525-89-4/ 605-494-5/ -	-	≤ 5 %	paraformaldehyde	Acute Tox. 4; H302 Skin Irr. 2; H315 Skin Sens. 1; H317 Eye Dam. 1; H318 Acute Tox. 4; H332 Resp. Sens. 1; H334

SECTION 4. First aid measures		
4.1.	Description of first aid measures	
General notes:	Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident. Immediately remove any clothing soiled by the product.	
Following inhalation:	Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness place patient stably in side position for transportation.	

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	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap and rinse thoroughly. If symptoms persist, consult a doctor.
	Following eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
	Following ingestion:	DO NOT induce vomiting. If symptoms persist, consult a doctor.
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	High concentration vapor inhalation may cause headache, dizziness, difficult breathing and unconsciousness.
	Following skin contact:	Causes skin irritation, redness, swelling. Prolonged or repeated contact causes defatting and dry skin.
	Following eye contact:	Vapors irritate eyes. Splashing may cause irritation and redness.
	Following ingestion:	Nausea, vomiting (danger of aspiration), diarrhoea. Aspiration may cause headache, vertigo, nausea, dazed feeling-unconsciousness/coma, possible hypothermia, reactions to the heart/circulatory system such as vasodilation (flush), hypotension, arrhythmia (possible ventricular fibrillation through cardiac sensitization), danger of central respiratory paralysis or of cardiac arrest; functional disturbance to the liver and kidneys and persistent disturbance to the CNS as sequelae.
4.3.	Indication of any immediate medical attention and special treatment needed	
	No further relevant information available.	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
	Unsuitable extinguishing media:	water with full jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous by products of fire:	Incomplete combustion of the product.
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4.	Additional information	
	Collect contaminated firefighting water separately. Do not contaminate the environment with extinguishing media.	

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 equipment:	Use personal protective equipment (see Section 8). Keep unprotected persons away.
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	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 materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and 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 tools that may cause sparks.
6.4.	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition. Carry out measures for preventing static electricity.
	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:	

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	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, and away from sources of heat, sunlight, and other incompatible substances.
	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.
	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).
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	
-	-	-	-	-
Substance:	-			
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				

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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	
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:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.	Personal protection equipment:	
8.2.2.1.	Eye and face protection:	Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU)
8.2.2.2.	Skin protection	

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	Hand protection:	Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Full contact: Glove material: Viton Glove thickness: 0.7 mm Break through time: 480 min Splash contact: Glove material: Nitrile rubber Glove thickness: 0.4 mm Break through time: 35 min
	Other skin protection:	Complete suit protecting against chemicals, flame retardant antistatic protective clothing (EN 13688). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
8.2.2.3.	Respiratory protection:	Where risk assessment shows air-purifying respirators are appropriate use type ABEK (EN 14387) respirator cartridges as a backup to engine protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as CEN (EU).
8.2.2.4.	Thermal hazards:	No information available
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:	liquid	No information available
	Colour:	colourless	No information available
	Odour:	formaldehyde odor	No information available
	Odour threshold:	No information available	No information available
	pH:	10.0 – 11.0	No information available

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	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 Pow):	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		
	-		

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	No relevant information available.
10.2.	Chemical stability:	The product is chemically stable under recommended storage conditions.
10.3.	Possibility of hazardous reactions:	No dangerous reactions known.
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	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results

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Oral:	No information available	rat	LD ₅₀	No information available	800 mg/kg (paraformaldehyde)
Dermal:	No information available	-	-	No information available	No information available
Inhalation:	No information available	rat	LD ₅₀	4h	1.07 mg/kg (paraformaldehyde)

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	No information available

Aspiration hazard:

-

Irritation and corrosion

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

Sensitization

Skin sensitization:	No information available
Respiratory sensitization:	No information available

Symptoms related to physical, chemical, and toxicological properties

Oral exposure:	Nausea, vomiting (danger of aspiration), diarrhoea. Aspiration may cause headache, vertigo, nausea, dazed feeling-unconsciousness/coma, possible hypothermia, reactions to the heart/circulatory system such as vasodilation (flush), hypotension, arrhythmia (possible ventricular fibrillation through cardiac sensitization), danger of central respiratory paralysis or of cardiac arrest; functional disturbance to the liver and kidneys and persistent disturbance to the CNS as sequelae.
Dermal exposure:	Causes skin irritation, redness, swelling. Prolonged or repeated contact causes defatting and dry skin.
Inhalation exposure:	Vapor inhalation may cause nose and throat irritation followed by sore throat, cough, difficult breathing and suffocating. High concentration vapor inhalation may cause headache, malaise and fatigue, difficult breathing, chest tightness, coordination and CNS disorders.

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Eye exposure:	Vapors irritate eyes. Splashing may cause irritation and redness, lacrimation, pain, swelling, blurred vision, photophobia.
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	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	-
Subchronic dermal	No information available	No information available	-

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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:	Suspected of causing cancer.
	Mutagenicity <i>in-vitro</i> :	No information available
	Genotoxicity:	No information available
	Mutagenicity <i>in-vivo</i> :	No information available
	Germ cell mutagenicity :	Suspected of causing genetic defects.
	Reproductive toxicity:	No information available
	Summary of evaluation of the CMR properties:	No information available

11.2.	Practical experiences:	
	Classification observations:	No information available
	Other observations:	No information available
11.3.	General notes:	
	-	

SECTION 12. Ecological information						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	fish	No information available	60 mg/l (paraformaldehyde)	-
Crustacea:	EC ₅₀	48 hours	-	No information available	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	No information available	-	-
Other organisms:	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note

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Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants:	IC ₅₀	72 hours	No information available	No information available	No information available	-
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	Extremely biodegradable.

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Pow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	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	-

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

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SECTION 13. Disposal considerations	
13.1.	Waste processing 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 Low:
	Disposal must be made according to official regulations.
13.1.3.	Waste tretment – 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:
	-
SECTION 14. Transport information	
	Transporting/shipment by road (ADR)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-

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Packing group:	-
Environmental hazards:	-
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:	-
Environmental hazards:	-
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 hazards:	-
Special precautions for user:	-
Transport in bulk condition in accordance with Annex II. of MARPOL 73/78 and IBC Codex:	-
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 hazards:	-
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
	Authorisation and/or restrictions on use
	Authorisations: -
	Restrictions: -

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Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2010 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); EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 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, Ordinance on writing Material safety data sheet, 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: PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative LD₅₀ Lethal dose, 50% LC₅₀ Lethal concentration, 50% STOT – SE 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> <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)				

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	H:	H302	Harmful if swallowed
		H315	Causes skin irritation
		H317	May cause an allergic skin reaction.
		H318	Causes serious eye damage
		H332	Harmful if inhaled
		H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
16.6.	Training advice:		-
16.7.	Further information:		** "X" in the product code marks different volumes (different packaging 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		
-		