

Trading name:	<b>REAGENT FOR DIFFERENTIATION IN GOMORI TRICHROME KIT</b>		
Product code:	RDG-OT-X**	Date of compilation:	21 Dec 2022
		Version:	4

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>	
1.1.	Product identifier
	Trading name: REAGENT FOR DIFFERENTIATION IN GOMORI TRICHROME KIT
	Chemical name: -
	Catalogue number: RDG-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against
	Uses: Reagent for differentiation.
	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
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: <a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact: -
1.4.	Emergency telephone number
	National Protection and Rescue Directorate: 112
	Medical information: +385 1 2348 342
	Other information: -

<b>SECTION 2. Hazards identification</b>	
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*:
	Not identified as hazardous substance. -
2.1.2.	Additional information
	-
*For full text of Hazard- and EU Hazard-statements: see Section 16	
2.2.	Label elements
	Product identification: REAGENT FOR DIFFERENTIATION IN GOMORI TRICHROME KIT
	Identification number: -
	Authorization no.: -
	Hazard pictograms: -

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Signal word:	-
Hazard statements:	-
Precautionary statements:	-
Further information:	-

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

<b>SECTION 3. Composition/information on ingredients</b>
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CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-19-7/ 200-580-7/ 607-002-00-6	-	0.2 – 0.3 %	acetic acid, glacial 99%	Flam. Liquid 3; H226 Skin Corr. 1A; H314

<b>SECTION 4. First aid measures</b>
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4.1.	Description of first aid measures
	General notes: -
	Following inhalation: No information available
	Following skin contact: No information available
	Following eye contact: No information available
	Following ingestion: No information available
	Self-protection of the first aider: Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed
	Following inhalation: No information available
	Following skin contact: No information available
	Following eye contact: No information available
	Following ingestion: No information available
4.3.	Indication of any immediate medical attention and special treatment needed
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<b>SECTION 5 Firefighting measures</b>
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5.1.	Extinguishing media
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	Suitable extinguishing media:	Small fire - water spray, dry powder, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	water jet
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	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

<b>SECTION 6. Accidental release measures</b>		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	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. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Wear 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 inflammable material (sand, diatomaceous earth, vermiculite). 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	

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	<p>See Section 7 for information about secure handling.</p> <p>See Section 8 for information about personal protective equipment.</p> <p>See Section 13 for information about containment.</p>
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<b>SECTION 7. Handling and storage</b>		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	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, 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 9).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

<b>SECTION 8. Exposure controls/personal protection</b>			
8.1.	Control parameters		
	Substance	CAS No	Occupational exposure limit values/short term values
	Biological limit values		

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		ppm	mg/m <sup>3</sup>	
-	-	-	-	No information available

Substance name:	-
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EC No:	-	CAS No:	-
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**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**

**8.2.1. Appropriate engineering controls**

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.
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	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.	<b>Personal protection equipment</b>	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
8.2.2.2.	<b>Skin protection</b>	
	Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	<b>Environmental exposure controls</b>	
	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

<b>SECTION 9. Physical and chemical properties</b>			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour/odour threshold:	No information available	No information available
	Melting point / freezing point:	No information available	No information available

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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
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
<b>9.2.</b>	<b>Other information</b>	
	-	

<b>SECTION 10. Stability and reactivity</b>		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
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:	No information available.

<b>SECTION 11. Toxicological information</b>					
<b>11.1. Information on toxicological effects</b>					
Acute toxicity:					
Route of exposure:	Method	Species	Effective dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral exposure:	No information available	-	LD <sub>50</sub>	-	-

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Dermal exposure:	No information available	-	LD <sub>50</sub>	-	-
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-	-

**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	-

**Respiratory irritation:** No information available

**Irritation and corrosion**

	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	-	-	-	-
Eye irritation:	-	-	-	-	-

**Sensitization**

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

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

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



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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	-

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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:	-
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**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.	-
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**11.2.2. Other informations:**

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**SECTION 12. Ecological information**

**12.1. Toxicity**

Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	-	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	-	-

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Algae/aquatic plants	IC <sub>50</sub>	8 days	No information available	No information available	-	-
Microorganisms	LC <sub>50</sub>	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	-	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	-	-
Other organisms	-	-	-	-	-	-

<b>12.2.</b>	<b>Persistence and degradability</b>
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	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				
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% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

<b>12.3.</b>	<b>Bioaccumulative potential</b>
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	Partition coefficient: n-octanol/water (log K <sub>ow</sub> ):				
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Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

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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						
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	-

**12.4. Mobility in soil**

Known or predicted distribution in environmental compartments:						
No information available						

Surface tension:						
Value	°C	Concentration	Method	Evaluation	Note	
No information available	No information available	No information available	No information available	-		

Adsorption / desorption						
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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	-

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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**

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.

**12.6. 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:**

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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:	-
Environmentally hazardous:	-
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:	-
Environmentally hazardous:	-
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:	-
Environmentally hazardous:	-
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:	-
Environmentally hazardous:	-
Special precautions for user:	-

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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:	-
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:	-
Other EU regulations:	<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)	

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	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	

<b>SECTION 16. Other information</b>		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
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)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H: 226 314	Flammable liquid and vapour. Causes severe skin burns and eye damage.
16.6.	Training advice:	-
16.7.	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.

<b>ANNEX:</b> <b>Exposure scenario resulting to Chemical safety assessment</b>
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