

Trade name:	DEHEMATIN				
Product code:	KO-OT-X**	Date of compilation:	27.05.2019.	Version:	3

SECTION 1. Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	DEHEMATIN
	Chemical name:	-
	Catalogue number:	KO-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Modified Kardasewitsch solution for depigmentation of acid hematein.
	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
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
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 (EC) Regulation No. 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Flam. Liq. 2	H225
	Skin Irrit. 2	H315
	Eye Irrit. 2	H319
	STOT SE 3	H335
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	DEHEMATIN

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Identification number:	-
Authorisation number:	-
Hazard pictograms:	 GHS02  GHS07
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation.
Precautionary statement:	P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. P233 Keep container tightly closed. 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. P314 Get medical advice/attention if you feel unwell.
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 (REGULATION) (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	-	> 65 %	ethanol	Flam. Liq. 2; H225
1336-21-6/ 215-647-6/ 007-001-01-2	-	≤ 5%	ammonia, 25 %	Skin Corr. 1B; H314 Aquatic Acute 1; H400

SECTION 4. First aid measures

4.1.	Description of first aid measures
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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 all contaminated clothes/footwear. Thoroughly wash with water for at least 15 minutes.
Following eye contact:	Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open. If the afflicted person wears contact lenses that are easy to remove, remove the lenses and continue rinsing.
Following ingestion:	If the afflicted person is vomiting, there may be risk of aspiration. Keep the airways open. Respiratory failure may occur immediately after aspiration of vomited content. 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	-

4.2.	Most important symptoms and effects, both acute and delayed	
Following inhalation:	Depending on concentration and exposure time, irritation of the mucous membrane of the nose/throat may occur (burning sensation, urge to sneeze, and runny nose). Very high concentration may cause difficult breathing, shortness of breath, coughing fits, chest tightness, headache, vertigo, and narcosis.	
Following skin contact:	Depending on concentration and exposure time, it may lead to redness, rough and cracked skin.	
Following eye contact:	Splatter may cause discomfort, stinging sensation, conjunctival redness, corneal surface lesions.	
Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting, vertigo, and headache.	
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
Suitable extinguishing media:	Small fire - water spray, dry powder, alcohol-resistant foam, CO ₂ 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:	-	
5.3.	Advice for firefighters	

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	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray, in order to prevent explosion.
5.4.	Additional information
	Remove sources of heat and ignition. 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
	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. 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 material for containment and cleaning up
6.3.1.	For creating barriers, covering and sealing: 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: Do not use incompatible materials (see Section 10).
6.4.	Reference to other sections
	-

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.

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	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.
	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	
Ethanol	64-17-5	1000/-	1900/-	No information available
Ammonia, anhydrous	(7664-41-7)	20/50	14/36	(no information available)
Substance: -				
EC No: - CAS No: -				
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic

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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.
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:	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	

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	Hand protection:	Protective gloves must be according to the Directive EU 2016/425/EEC and standard EN 374. Full contact: Gloves material: Viton Glove thickness: 0.70 mm Time until perforation: >480 min Splashing: Glove material: butyl rubber Glove thickness: 0.70 mm Time until perforation: > 240 min
	Other skin protection:	Wear full protective suit that protects from chemicals (EN 340) and shoes that cover the entire foot. Choose the protective clothes according to concentration and amount of hazardous substances present at workplace.
8.2.2.3.	Respiratory protection:	Full face mask (EN 136) or half mask (EN 140) equipped with a recommended "AX" filter (EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	-
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties

9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour:	ethanolic	No information available
	Odor threshold:	no information available	No information available
	pH:	no information available	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:	21 °C	No information available

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	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		
	-		

SECTION 10. Stability and reactivity		
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 (room temperature).
10.3.	Possibility of hazardous reactions:	May cause hazardous reactions in contact with strong bases.
10.4.	Conditions to avoid:	Heat, spark, open flame, strong heating, ignition sources.
10.5.	Incompatible materials:	Strong oxidizing agents, alkali metals.
10.6.	Hazardous decomposition products:	Non-degradable if used in the described manner.

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 (ethanol) rat (ammonia)	LD ₅₀	4 h (ethanol)	6.200 mg/kg (ethanol) 350 mg/kg (ammonia, 29% solution)
Dermal:	No information available	No information available	LD ₅₀	No information available	> 20.000 mg/kg (ethanol)
Inhalation:	No information available	rat (ethanol) rat (ammonia)	LC ₅₀	4 h (ethanol) 1 h (ammonia)	> 8.000 mg/L (ethanol) 7,338 ppm (ammonia)

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: May cause respiratory irritation.

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	-

Skin sensitization:

Dermal:	May cause skin irritation.
Respiratory sensitization:	Allergic persons may display irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Depending on concentration and exposure period, it may lead to kidney and liver disorders.
Dermal exposure:	Depending on concentration and exposure time, redness accompanied by sensation of stinging and pain may occur, defatting, skin cracking, rash, swelling, burns, blisters and delayed onset of inflammations.

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Inhalation exposure:	Depending on concentration and exposure period, it may cause vertigo, nausea, disorientation.
Eye exposure:	Depending on concentration and exposure period, it may lead to mucosa stinging, tearing, redness and pain.

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):

	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	-

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

	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

11.2.	Practical experiences:	
	Remarks relevant for classification:	No information available
	Other remarks:	No information available
11.3.	Note:	
	-	

SECTION 12. Ecological information:						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	No information available	8140 mg/l (ethanol)	-
Crustacea:	EC ₅₀	48 hours	<i>Daphnia magna</i> (water flea)	No information available	9268 – 14221 mg/l (ethanol)	-
Algae/aquatic plants	IC ₅₀	72 hours	-	No information available	5000 mg/l (ethanol)	-

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Microorganisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
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	-
Microorganisms	-	-	-	-	-	-

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
91	1	OECD (anaerobic conditions)	-	ethanol

12.3. Bioaccumulative potential

	Partition coefficient: n-octanol/water (log Kow):					
Value	Concentration	pH	°C	Method	Evaluation	Note
- 0.31	-	-	25	-	-	ethanol

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note

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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 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	

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12.6.	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. Material must be disposed of in compliance with the respective national regulations.
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:
	-

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	1170

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UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazardous:	-
Special precautions for user:	-

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
	Authorisation and/or restrictions on use
	Authorisations:
	-

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	Restrictions:	-
	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. 453/2006 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); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council from 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about 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.
		LD ₅₀	Lethal dose, 50%
		LC ₅₀	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)		
Classification		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		

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	H:	H225 H314 H315 H319 H335 H400	Highly flammable liquid and vapor. Causes severe skin burns and eye damage Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. Very toxic to aquatic life.
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.	

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT

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