

HEMATOXYLIN W KIT

VERSION 3

The kit contains:

Hematoxylin, Weigert A

Ferri reagent, Weigert B

Trade name:	HEMATOXYLIN, WEIGERT A				
Product code:	HEMA-OT-X**	Date of compilation:	19 Dec 2023	Version:	6


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

1.1.	Product identifier	
	Trade name:	HEMATOXYLIN, WEIGERT A
	Chemical name:	-
	Catalogue number:	HEMA-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in special staining kits.
	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 Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Flam. Liq. 2	H225
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	HEMATOXYLIN, WEIGERT A
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	 GHS02
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statement:	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
Supplemental hazard information (EU)	-

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

SECTION 3. Composition/information on ingredients

CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
107-21-1/ 203-473-3/ 603-027-00-1	01-2119456816- 28-xxxx	1- 10 %	ethylene glycol	Acute Tox. 4, H302
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610- 43-0147	60 – 80 %	ethanol	Flam. Liq. 2, H225

SECTION 4. First aid measures

4.1.	Description of first aid measures
	<p>General notes: If the suggested first aid measures do not prove sufficient, seek medical attention.</p> <p>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.</p> <p>Following skin contact: Remove contaminated clothing. Thoroughly wash with water for 15 minutes.</p>

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Following eye contact:	Rinse the eyes using mild jet of clean water for at least 15 minutes with the eyelids held wide open.
Following ingestion:	Rinse the mouth thoroughly with water. If the afflicted person is conscious, provide them with large amounts of water. Consult a physician.
Self-protection of the first aider	-

4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	May cause eye irritation and upper respiratory system (stinging sensation, irritation). Bronchoconstriction is possible. Possible symptoms include CNS symptoms such as headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration.
	Following skin contact:	Defatting, dry skin.
	Following eye contact:	Splatter may cause discomfort, stinging sensation, conjunctival redness, corneal surface lesions.
	Following ingestion:	It may lead to occurrence of strong sensation of stinging, headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration. If denaturants are present, dyspepsia may occur (such as vomiting).
4.3.	Indication of any immediate medical attention and special treatment needed	
	No information available	

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:	Incomplete combustion of the product.
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	
	-	

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:	When disposing of small quantities use protective clothing. When disposing of large quantities use self-contained open-circuit compressed air breathing apparatus or self-contained closed-circuit air breathing apparatus.
	Accident prevention methods:	Secure a safety zone, remove all ignition sources, and in case of an accident inform the Emergency service (112) and the manufacturer or sender. Position a prohibition sign with symbols of flame and devices that cause sparks.
	Emergency procedures:	Remove or neutralize all factors that may exacerbate the condition, use all allowed means of containing the situation and use recommended means of personal protection.
6.1.2.	For emergency responders:	
		Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).
6.2.	Environmental precautions:	
		Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112).
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:	Keep away from sources of ignition and heat. Do not use tools that cause sparks.
	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.

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7.2.	Conditions for safe storage, including any incompatibilities			
	Technical measures and storage conditions:	Keep in a well-ventilated place. Keep away from heat and direct solar radiation.		
	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:	-		
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/-	-
	Ethylene glycol	107-21-1	20/40	52/104	-
	Substance:	-			
	EC No:	-	CAS No:	-	
DNEL					
Industrial					
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic	
Oral	-	-	-	-	
Inhalation	1900 mg/m ³ (ethanol)	-	35 mg/kg (ethylene glycol)	380 mg/m ³ (ethanol)	
Dermal	-	-	-	343 mg/kg (ethanol) 106 mg/kg (ethylene glycol)	
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	950 mg/m ³ (ethanol)	-	7 mg/kg (ethylene glycol)	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol) 53 mg/kg (ethylene glycol)

PNEC

Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol) 10 mg/l (ethylene glycol)
Freshwater sediments	3.6 mg/kg (ethanol) 37 mg/kg (ethylene glycol)
Marine water	0.79 mg/l (ethanol) 1 mg/l (ethylene glycol)
Marine sediments	2.9 mg/kg (ethanol) 3.7 mg/kg (ethylene glycol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol) 199.5 mg/l (ethylene glycol)
Soil (agricultural)	0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene glycol)
Air	no information available

8.2. Exposure controls

8.2.1. Engineering measures

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:	See Section 7.2

8.2.2. Personal protection equipment

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8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN166) 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:	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:	During everyday work use cotton clothing and suitable footwear, such as rubber boots or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
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.	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:	brown	No information available
	Odour/odour threshold:	ethanol like/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available

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Lower and upper explosion limit:	No information available	No information available
Flash point:	20°C	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

9.2.	Other information
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SECTION 10.: Stability and reactivity

10.1.	Reactivity:	The product is stable under normal working and storage conditions.
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:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.
10.4.	Conditions to avoid:	High temperatures, ignition sources, open flame.
10.5.	Incompatible materials:	Oxidants, acids, alkali metals.
10.6.	Hazardous decomposition products:	Non-degradable if used in the described manner.

SECTION 11. Toxicological information

11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008				
	Acute toxicity:				
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	No information available	rat	LD ₅₀	-	7.060 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol)

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Dermal:	No information available	rabbit	LD ₅₀	-	>20.000 mg/kg (ethanol) >3.500mg/kg (ethylene glycol)
Inhalation:	No information available	rat	LC ₅₀	4 h (ethanol)	>8.000 mg/l (ethanol)

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:	-	-	-	-	No information available
Serious eye damage/irritation	-	-	-	-	No information available

Sensitization:

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

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	It may lead to occurrence of strong sensation of stinging, headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration. If denaturants are present, dyspepsia may occur (such as vomiting).
Dermal exposure:	Defatting, dry skin.
Inhalation exposure:	May cause eye irritation and upper respiratory system (stinging sensation, irritation). Bronchoconstriction is possible. Possible symptoms include CNS symptoms such as headache, vertigo, intoxication and loss of consciousness after exposure to higher levels of concentration.
Eye exposure:	Splatter may cause discomfort, stinging sensation, conjunctival redness, corneal surface lesions.

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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	-
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:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
	-

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	8.140 mg/l (ethanol) 72.860 mg/l (ethylene glycol)	-
Crustacea:	EC ₅₀	48 hours	water flea	No information available	7.800 mg/l (ethanol) >100 mg/l (ethylene glycol)	-
Algae/aquatic plants	IC ₅₀	72 hours	algae	No information available	5.000 mg/l (ethanol) 6.500-13.000 mg/l (ethylene glycol)	-
Microorganisms	-	-	No information available	No information available	No information available	-

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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
-	-	-	-	-

12.3. Bioaccumulative potential

Partition coefficient: n-octanol/water (log K_{ow}):

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

Bioconcentration factor (BCF)

Value	Species	Method	Evaluation	Note

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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 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						
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.						

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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 adverse effects are expected.

SECTION 13. Disposal considerations

13.1.	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2.	Waste codes/waste designations according to Law:
	No information available

13.1.3.	Waste treatment – relevant information:
	No information available

13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.

13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.

13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution

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Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
Special precautions for user:	-

Transporting/shipment by rail (RID)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
Special precautions for user:	-

Transporting/shipment by inland waterways (ADN)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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 hazards:	No information available
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:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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	
	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)	
	National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment	
	None	

SECTION 16. Other information

16.1.	Indication of changes:	-
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16.2.	Abbreviations and acronyms:	and	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
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:	225 302	Highly flammable liquid and vapor. Harmful if swallowed.
16.6.	Training advice:		-
16.7.	Further information:		<p>** "X" in the product code marks different volumes (different packaging 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>

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT

-

Trading name:	FERRI REAGENT, WEIGERT B				
Product code:	FR-OT-X**	Revision date:	21 Dec 2022	Version:	5

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier	
Trading name:	FERRI REAGENT, WEIGERT B
Chemical name:	-
Catalogue number:	FR-OT-X**
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Uses:	For use in special staining kits.
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:	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 INFORMATION

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. Classification according to EC Directive Nr. 1272/2008 CLP)	
Product identification:	FERRI REAGENT, WEIGERT B
Identification number:	-
Authorization no.:	-
Hazard pictograms:	-

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Signal word:	-
Hazard statements:	-
Precautionary statements:	-
Supplemental hazard information (EU):	-

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

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
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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)
7782-61-8/ 616-509-1/ -	-	< 0.5%	ferric nitrate nonahydrate	Skin Irrit. 2; H315 Eye Irrit. 2; H319
7647-01-0/ 231-595-7/ 017-002-00-2	01-2119484862- 27-xxxx	< 1%	hydrochloric acid, 37%	Skin Corr. 1B; H314 STOT SE 3; H335

SECTION 4 FIRST AID MEASURES	
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4.1.	Description of first aid measures
	<p>General notes: -</p> <p>Following inhalation: Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.</p> <p>Following skin contact: Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.</p> <p>Following eye contact: Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.</p> <p>Following ingestion: Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.</p> <p>Self-protection of the first aider: Treat symptomatically.</p>
4.2.	Most important symptoms and effects, both acute and delayed

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Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.
Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.
Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.
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, 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: 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.

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. 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).

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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.	Bundling, 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	
	-	

SECTION 7 HANDLING AN STORAGE		
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.

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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 9).
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	
Hydrogen chloride	7647-01-0	5/10	8/15	-
Substance name:	-			
EC No:	-	CAS No:	-	

DNEL

Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available

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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
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8.2.1.	Engineering measures
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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:	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
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8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
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8.2.2.2.	Skin protection
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	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.
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8.2.2.4.	Thermal hazards:	No information available
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8.2.3.	Environmental exposure controls
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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:	pale yellow	No information available
	Odour/odour threshold:	neutral/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
	-		

SECTION 10 STABILITY AND REACTIVITY

10.1.	Reactivity:	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:	With strong oxidants, sodium-hydroxide, sulfuric acid, aluminum.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Aluminum.

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10.6.	Hazardous decomposition products:	No information available.
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SECTION 11 TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity:

Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-

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:	-	rabbit	-	-	-
Eye irritation:	-	rabbit	-	-	-

Sensitization

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

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.
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Dermal exposure:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.
Inhalation exposure:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
Eye exposure:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.

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	-

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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	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.
Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	Current <i>in vivo</i> tests did not indicate mutagenic effects.
Germ cell mutagenicity:	No information available
Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.

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.

11.2.2. Other information:

-

SECTION 12 ECOLOGICAL INFORMATION:

12.1. Toxicity

Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
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Trading name:	FERRI REAGENT, WEIGERT B				
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Fish	LC ₅₀	96 hours	-	No information available	-	-
Crustacea:	EC ₅₀	48 hours	-	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	-	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic 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	-
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

Trading name:	FERRI REAGENT, WEIGERT B				
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Partition coefficient: n-octanol/water (log Kow):						
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	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 (<i>Daphnia</i>)	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
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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

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: The product is not subject to classification.	

SECTION 15 REGULATORY INFORMATION	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -
	<p>Other EU regulations:</p> <p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)
	National legislation: Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment

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None

SECTION 16 Other information		
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: H314	Causes severe skin burns and eye damage.
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.
	H335	May cause respiratory irritation.
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.

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-