

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1.	Product identifier	
	Trading name:	SODIUM ACETATE, SOLUTION
	Chemical name:	-
	Catalogue number:	NA-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Rhodanine kit.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, 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 (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:	SODIUM ACETATE, SOLUTION
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	-
	Signal word:	-

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

	Hazard statements:	-
	Precautionary statements:	-
	Further information:	-
2.3.	Other hazards	
	-	

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
-	-	-	-	-

SECTION 4 FIRST AID MEASURES		
4.1.	Description of first aid measures	
	General notes:	-
	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.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.
	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.
	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.
	Self-protection of the first aider:	Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed	
	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.

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

	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).	
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.

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

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.
	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:	-

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

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	
-	-	-	-	No information available
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		
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			

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

8.2.1.	Engineering measures	
	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 (preventing splashing) (EN 166) or visor.
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:	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.	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
	Color:	colourless	No information available

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

Odor:	no odor	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:	No information available	No information available
Evaporation rate:	No information available	No information available
Flammability (solid, gas):	No information available	No information available
Upper/lower flammability or explosive limits:	No information available	No information available
Vapor pressure:	No information available	No information available
Vapor 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):	Soluble in water (20 °C)	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.
10.3.	Possibility of hazardous reactions:	With strong oxidants, sodium-hydroxide, sulfuric acid, aluminum.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
10.6.	Hazardous decomposition products:	No information available.

SECTION 11 TOXICOLOGICAL INFORMATION	
11.1.	Information on toxicological effects
	Acute toxicity:

Trading name:	SODIUM ACETATE, SOLUTION				
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version:	4

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

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 discomfort in abdomen and abdominal pains.
Dermal exposure:	Allergic persons may display irritation.
Inhalation exposure:	Allergic persons may display irritation after prolonged or repeated exposure.
Eye exposure:	May cause irritation.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
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Trading name:	SODIUM ACETATE, SOLUTION					
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version:	4	

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)

Trading name:	SODIUM ACETATE, SOLUTION					
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version:	4	

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

SECTION 12 ECOLOGICAL INFORMATION:						
12.1.	Toxicity					
Acute 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	8 days	No information available	No information available	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	-

Trading name:	SODIUM ACETATE, SOLUTION					
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version:	4	

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

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

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	Species	Method	Evaluation	Note
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Trading name:	SODIUM ACETATE, SOLUTION					
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version:	4	

		time				
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 K _{ow}	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					
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SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

	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:	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.

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

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:	-

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.
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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: -

Trading name:	SODIUM ACETATE, SOLUTION			
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version: 4

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: <table> <tr> <td>PBT</td><td>Stable, bioaccumulative and toxic</td></tr> <tr> <td>vPvB</td><td>Strongly stable and strongly bioaccumulative.</td></tr> <tr> <td>LD₅₀</td><td>Lethal dose, 50%</td></tr> <tr> <td>LC₅₀</td><td>Lethal concentration, 50%</td></tr> <tr> <td>STOT-SE</td><td>Specific target organ toxicity - single exposure</td></tr> </table>	PBT	Stable, bioaccumulative and toxic	vPvB	Strongly stable and strongly bioaccumulative.	LD ₅₀	Lethal dose, 50%	LC ₅₀	Lethal concentration, 50%	STOT-SE	Specific target organ toxicity - single exposure
PBT	Stable, bioaccumulative and toxic										
vPvB	Strongly stable and strongly bioaccumulative.										
LD ₅₀	Lethal dose, 50%										
LC ₅₀	Lethal concentration, 50%										
STOT-SE	Specific target organ toxicity - single exposure										
16.3.	Key literature references and source of data: -										
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)										
<table> <tr> <th>Classification</th><th>Classification procedure</th></tr> <tr> <td>-</td><td>-</td></tr> </table>		Classification	Classification procedure	-	-						
Classification	Classification procedure										
-	-										
16.5.	Relevant H statements (number and full text)										
	H: -										
16.6.	Training advice: -										

Trading name:	SODIUM ACETATE, SOLUTION				
Product code:	NA-OT-X**	Date of compilation:	05 July 2019	Version:	4

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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ANNEX: EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT	
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Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING		
1.1	Product identifier	
	Trading name:	4% NB FORMALDEHYDE
	Chemical name:	-
	Catalogue number:	FNB4-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Fixative for use in histology.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
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 (EC) Regulation No. elements	
	Hazard class and category code:	Hazard statements*:
	Carc. 2	H351
	Acute Tox. 4	H332
	Acute Tox. 4	H312
	Acute Tox. 4	H302
	Eye Irrit. 2	H319
	Skin Irrit. 2	H315
	Skin Sens. 1	H317
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		

Trading name:	4% NB FORMALDEHYDE			
Product code:	FNB4-X**	Revision date:	13 May 2019	Version: 5

2.2	Label elements	
	Product identification:	4% NB FORMALDEHYDE (10% neutral buffered and stabilized formalin solution, pH 7.0)
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	
	Signal word:	Warning
	Hazard statements:	H302 Harmful if swallowed. H312 Harmful in contact with skin. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H332 Harmful if inhaled. H351 Suspected of causing cancer.
	Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER/physician if you feel unwell. P403 Store in a well-ventilated place.
	Further information:	-
2.3	Other hazards	
	-	

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS				
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
50-00-0/ 200-001-8/ 605-001-00-5	01-2119488953-20-XXXX	< 5	formaldehyde, 37 %	Carc. 1B, H350 Muta. 2, H341 Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr. 1B; H314 Skin. Sens. 1, H317

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

67-56-1/ 200-659-6/ 603-001-00-X	01-2119433307-44-XXXX	< 1	methanol	Flam. Liq. 2; H225 Acute Tox. 3; H331 Acute Tox. 3; H311 Acute Tox. 3; H301 STOT SE 1; H370
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SECTION 4 FIRST AID MEASURES

4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. 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, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
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:	No information available

Trading name:	4% NB FORMALDEHYDE			
Product code:	FNB4-X**	Revision date:	13 May 2019	Version: 5

5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Not flammable. Surrounding fire may cause hazardous fumes to be released.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	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. 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.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	-	

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.		

Trading name:	4% NB FORMALDEHYDE			
Product code:	FNB4-X**	Revision date:	13 May 2019	Version: 5

	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. Avoid metal containers.
	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	
Formaldehyde	50-00-0	2	2.5	-
Methanol	67-56-1	200	260	24.7 mmol/mol of creatinine* (7.0 mg/g of creatinine*), end-of-shift urinary excretion
* For all results pertaining creatinine levels, creatinine concentration < 0.5 g/l and > 3.0 g/l may not be taken into consideration				
Substance name:	-			
EC No:	-	CAS No:	-	
DNEL				

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	1 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)	260 mg/m ³ (methanol)	0.5 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)	9 mg/m ³ (formaldehyde) 260 mg/m ³ (methanol)
Dermal	-	40 mg/kg (methanol)	0.037 mg/cm ² (formaldehyde)	240 mg/kg (formaldehyde) 40 mg/kg (methanol)

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	8 mg/kg (methanol)	-	4.1 mg/kg (formaldehyde) 8 mg/kg (methanol)
Inhalation	50 mg/m ³ (methanol)	50 mg/m ³ (methanol)	0.1 mg/m ³ (formaldehyde) 50 mg/m ³ (methanol)	3.2 mg/m ³ (formaldehyde) 50 mg/m ³ (methanol)
Dermal	-	8 mg/kg (methanol)	0.012 mg/cm ² (formaldehyde)	120 mg/kg (formaldehyde) 8 mg/kg (methanol)

PNEC

Environmental protection target	PNEC
Fresh water	0.47 mg/l (formaldehyde) 154 mg/l (methanol)
Freshwater sediments	2.44 mg/kg (formaldehyde) 570.4 mg/kg (methanol)
Marine water	0.47 mg/l (formaldehyde) 15.4 mg/l (methanol)
Marine sediments	2.44 mg/kg (formaldehyde)
Food chain	No information available
Microorganisms in sewage treatment	0.19 mg/l (formaldehyde) 100 mg/l (methanol)
Soil (agricultural)	0.21 mg/kg (formaldehyde) 23.5 mg/kg (methanol)
Air	No information available

8.2 Exposure controls

8.2.1. Engineering measures

Trading name:	4% NB FORMALDEHYDE			
Product code:	FNB4-X**	Revision date:	13 May 2019	Version: 5

	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.
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	
	Hand protection:	Protective nitrile gloves, 0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Suitable mask (EN 136) or half mask (EN 140) equipped with a combined "A1 + Form" filter (EN 143) 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:	transparent	No information available
	Odour:	sharp	No information available
	Odor threshold:	No information available	No information available
	pH:	6.8-7.2 (neutral buffered)	No information available

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	cca 100 °C at 1,013 hPa	No information available
	Flash point:	Not applicable	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	completely soluble in water	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		
	4% NB Formaldehyde (10% neutral buffered and stabilized formalin solution) is non-flammable aqueous solution because it is stabilized using methanol in concentration <1%.		

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:	Acids, nitrogen oxides, hydrogen peroxide, oxidizing agents, polymerization initiators, alkaline metals.
10.4	Conditions to avoid:	Heat sources, low temperatures.
10.5	Incompatible materials:	Various metals, alloys, plastic, magnesium, zinc alloys.
10.6	Hazardous decomposition products:	No information available.

SECTION 11 TOXICOLOGICAL INFORMATION	
11.1	Information on toxicological effects
	Acute toxicity:

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat	LD ₅₀	No information available	100 mg/kg (formaldehyde) 100.1 mg/kg (methanol)
Dermal:	-	rabbit	LD ₅₀	No information available	300.1 mg/kg (formaldehyde) 17,100 mg/kg (methanol)
Inhalation:	-	rat	LC ₅₀	4 h	3.1 mg/l (formaldehyde) 131.25 mg/l (methanol)

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:	-	-	-	-	Causes skin irritation.
Serious eye damage/irritation	-	-	-	-	Causes eye irritation.

Sensitization

Skin sensitization:	May cause allergic skin reaction.
Respiratory sensitization:	Allergic persons may display irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, nausea, vomiting.
Dermal exposure:	Depending on concentration and exposure time, redness accompanied by sensation of stinging and pain may occur, as well as skin cracking and rash.

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

Inhalation exposure:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
Eye exposure:	Depending on concentration and exposure time, it may lead to stinging, tearing, 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	-
Subchronic oral	No information available	No information available	-

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

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:	Suspected of causing cancer.		
Mutagenicity <i>in vitro</i> :	No information available		
Genotoxicity:	No information available		
Mutagenicity <i>in vivo</i> :	No information available		
Germ cell mutagenicity:	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	General notes:
-	

SECTION 12 ECOLOGICAL INFORMATION:						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	fish (<i>Lepomis macrochirus</i>)	-	15.400 mg/l (methanol)	-
Crustacea:	EC ₅₀	48 hours	water flea (<i>Daphnia magna</i>)	-	>10.000 mg/l (methanol)	-
Algae/aquatic plants	IC ₅₀	4 days	green algae	-	~22.000 mg/l (methanol)	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

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

Partition coefficient: n-octanol/water (log Kow):

Value	Concentration	pH	°C	Method	Evaluation	Note
0,021	-	-	-	formaldehyde	-	-
-0.77	-	-	-	methanol	-	-

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
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
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
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Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

	No information available
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.
13.1.2.	Waste codes/waste designations according to Law:
	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:	Not applicable
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

UN number:	Not applicable
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

	Inland waterway transport (ADN)
UN number:	Not applicable
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

	Transporting/shipment by sea (IMDG)
UN number:	Not applicable
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-

	Transporting/shipment by air (ICAO-TI/IATA-DGR)
UN number:	3334
UN proper shipping name:	Aviation regulated liquid, n.o.s. (formaldehyde)
Transport hazard class(es):	9
Packing group:	III
Environmentally hazardous:	None
Special precautions for user:	no information

Further information:	Formaldehyde solutions, nonflammable, containing less than 25% of formaldehyde do not adhere to the ADR regulations.
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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

Trading name:	4% NB FORMALDEHYDE			
Product code:	FNB4-X**	Revision date:	13 May 2019	Version: 5

	Authorizations:	-
	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 according to CLP		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		

Trading name:	4% NB FORMALDEHYDE				
Product code:	FNB4-X**	Revision date:	13 May 2019	Version:	5

H:	225	Highly flammable liquid and vapor.
	301	Toxic if swallowed.
	302	Harmful if swallowed.
	311	Toxic in contact with skin.
	312	Harmful in contact with skin.
	314	Causes severe skin burns and eye damage
	315	Causes skin irritation.
	317	May cause allergic skin reaction.
	319	Causes serious eye irritation.
	331	Toxic if inhaled.
	332	Harmful if inhaled.
	341	Suspected of causing genetic defects.
	350	May cause cancer.
	351	Suspected of causing cancer.
	370	Causes damage to organs.
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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Page 1 of 10

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	RHODANINE REAGENT
	Chemical name:	-
	Catalogue number:	RR-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Rhodanine kit.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, 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:	RHODANINE REAGENT
	Identification number:	-
	Authorization number:	-

Page 1 of 10

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

Hazard pictograms:	
	GHS02
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statements:	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.
Supplemental hazard information (EU):	-
2.3	Other hazards
	-

SECTION 3. Composition/information on ingredients

CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- xxxx	≥ 50% - <100 %	ethanol	Flam. Liq. 2; H225

SECTION 4. First aid measures

4.1	Description of first aid measures
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

	Following ingestion:	Rinse the mouth thoroughly with 1-2 glasses of water. 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, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
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 with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Formation of toxic gases is possible during heating or in case of fire.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

	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.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. 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:	Protect against electrostatic charges.
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. Protect from heat and direct sunlight.

Page 5 of 10

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

	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/-	-
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	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)
PNEC				

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	0.63 mg/kg (ethanol)
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:	In accordance with Section 7.
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.

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	
Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) 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.

Page 7 of 10

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

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:	orange	No information available
	Odour:	alcohol like	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:	17 °C	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapour pressure:	No information available	No information available
	Vapour density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

	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:	No dangerous reactions known.
10.4	Conditions to avoid:	Avoid heat, sparks, open flames and other ignition sources.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

SECTION 11. Toxicological information						
11.1	Information on toxicological effects					
	Acute toxicity:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results	
Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg	
Dermal:	-	-	-	-	-	
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	20.000 mg/l	
	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:	-	-	-	-	-	-

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

Serious eye damage/irritation	-	-	-	-	-
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Sensitization

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

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

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

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		-
Chronic dermal	No information available			No information available		-
Chronic inhalation	No information available			No information available		-
	CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)					
	Carcinogenicity:		Based on available data, the classification criteria are not met.			
	Mutagenicity <i>in vitro</i> :		Based on available data, the classification criteria are not met.			
	Genotoxicity:		Based on available data, the classification criteria are not met.			
	Mutagenicity <i>in vivo</i> :		Based on available data, the classification criteria are not met.			
	Germ cell mutagenicity:		Based on available data, the classification criteria are not met.			
	Reproductive toxicity:		Based on available data, the classification criteria are not met.			
	Summary of evaluation of the CMR properties:		Based on available data, the classification criteria are not met.			
11.2	Practical experiences:					
	Classification observations:		No information available			
	Other observations:		No information available			
11.3	General notes:					
	-					

SECTION 12. Ecological information	
12.1	Toxicity

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

Acute (short-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	4 days	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-
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	-
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

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

12.3	Bioaccumulative potential						
	Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note	
-	-	-	-	-	-	-	
	Bioconcentration factor (BCF)						
Value	Species		Method		Evaluation	Note	
No information available	No information available	information	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	-		

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

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

Not applicable.

12.6 Other adverse effects

No further relevant 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:

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:

Disposal must be made according to official regulations.

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

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
Environmentally hazardous:	-
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
Environmentally 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
Environmentally 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
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

SECTION 15. Regulatory information		
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; 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:	-

Trading name:	RHODANINE REAGENT				
Product code:	RR-OT-X**	Revision date:	05 July 2019	Version:	5

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:	Manufacturer's MSDS file.	
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:	H225	Highly flammable liquid and vapor.
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
-

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trading name:	HEMATOXYLIN M
	Chemical name:	-
	Catalogue number:	HEMM-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Modified hematoxylin acc. to Mayer for nuclear staining.
	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 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*:
	Acute Tox. 4	H302
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	HEMATOXYLIN M
	Identification number:	-
	Authorization number:	-

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

Hazard pictograms:	
	GHS07
Signal word:	Warning
Hazard statements:	H302 Harmful if swallowed.
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
Further information:	-
2.3.	Other hazards
	-

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
302-17-0/ 206-117-5/ 605-014-00-6	-	<5	chloral hydrate	Acute Tox. 3; H301 Skin Irrit. 2; H315 Eye Irrit. 2; H319

SECTION 4. First aid measures	
4.1.	Description of first aid measures
General notes:	-
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.
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.
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.
Following ingestion:	Provide the person with water (2 glasses at most). Immediately consult a physician. In extreme case, if medical assistance is not available within 1 hour, induce vomiting (only if the person is fully awake and conscious), apply activated charcoal (20-40 g in a 10% solution) and consult a physician as soon as possible.

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

	Self-protection of the first aider:	Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed	
	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:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Hydrochloride and phosgene may be released in case of fire.
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:	

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

	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:	Cap the drains. Collect, nuddle and pump out everything that got spilled.
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	
	For indications of waste processing see Section 13.	

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 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.

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

	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	
-	-	-	-	-
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		
Marine sediments		No information available		

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

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 (preventing splashing) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the EU Directive EU 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥ 0.40 mm Permeation period: > 480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves, and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	During long-term exposure wear a protective mask or a half mask equipped with filter A.
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

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

		Value	Method
	Physical state:	liquid	No information available
	Color:	red	No information available
	Odor:	No odor	No information available
	Odor threshold:	No information available	No information available
	pH:	2.0 - 2.5	No information available
	Melting point / freezing point:	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	Vapor pressure:	No information available	No information available
	Vapor 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):	Soluble in water (20 °C)	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
	Oxidizing 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:	With strong oxidants, sodium-hydroxide, sulfuric acid, aluminum.
10.4.	Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5.	Incompatible materials:	Aluminum.
10.6.	Hazardous decomposition products:	No information available.

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

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
Oral:	No information available	rat	LD ₅₀	-	479 mg/kg (chloral hydrate)
Dermal:	No information available	rat	LD ₅₀	-	3,030 mg/kg (chloral hydrate)
Inhalation:	No information available	-	LC ₅₀	-	-
	Specific target organ toxicity – single exposure (STOT SE):				
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
	Aspiration hazard:		No information available		
	Irritation and corrosion				
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-
	Sensitization				
Skin sensitization:	No information available				
Respiratory sensitization:	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.				

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

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.

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Repeated dose toxicity (subacute, subchronic, chronic)
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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

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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	-

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

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 tests</i> did not indicate mutagenic effects.
	Genotoxicity:	No information available
	Mutagenicity <i>in vivo</i> :	Current <i>in vivo tests</i> 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:	-

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

SECTION 12. Ecological information						
12.1.	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	<i>Leuciscus idus</i>	No information available	1,720 mg/l (chloral hydrate)	-
Crustacea:	EC ₅₀	48 hours	water flea	No information available	510 mg/l (chloral hydrate)	-
Algae/aquatic plants	IC ₅₀	8 days	green algae	No information available	2.8 mg/l (chloral hydrate)	-

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

Other organisms	LC ₅₀	72 hours	-	-	-	-
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	-
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

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)

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

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
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

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

	No information available
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.
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:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

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:	-
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:
	-

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

	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% STOT-SE Specific target organ toxicity - single exposure
16.3.	Key literature references and source of data:		-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
Classification		Classification procedure	
-		-	
16.5.	Relevant H statements (number and full text)		
	H:	H302	Harmful if swallowed.

Trading name:	HEMATOXYLIN M				
Product code:	HEMM-OT-X**	Revision date:	07.05.2019.	Version:	6

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	
-	