

## SUDAN BLACK B KIT

The kit contains:

Acetone for histology

Glutaraldehyde, 4% buffered solution

Hematoxylin G3



Sudan Black B reagent

Trading name:	<b>ACETONE FOR HISTOLOGY</b>				
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>		
1.1	Product identifier	
	Trading name:	ACETONE FOR HISTOLOGY
	Chemical name:	propanone
	Catalogue number:	AC-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with special staining kits.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

<b>SECTION 2. Hazards identification</b>		
2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Flam. Liq. 2	H225
	Eye Irr. 2	H319
	STOT SE 3	H336
		EUH066
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	ACETONE FOR HISTOLOGY

Trading name:	<b>ACETONE FOR HISTOLOGY</b>				
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

Identification number:	-
Authorization number:	-
Hazard pictograms:	 
	GHS02                      GHS07
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness.
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. Do not smoke. P280 Wear protective gloves/protective clothing/eye/protection/face protection. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/attention.
Supplemental hazard information (EU):	EUH066 Repeated exposure may cause skin dryness or cracking.
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)
67-64-1/ 200-662-2/ 606-001-00-8	-	100 %	acetone	Flam. Liq. 2; H225 Eye Irr. 2; H319 STOT SE 3; H336 EUH066

**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.

Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

	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:	Do not induce vomiting. Do not insert any object into the unconscious person's mouth. 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:	-

<b>4.2</b>	<b>Most important symptoms and effects, both acute and delayed</b>
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	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Defatting, dry skin.
	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.

<b>4.3</b>	<b>Indication of any immediate medical attention and special treatment needed</b>
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<b>SECTION 5. Firefighting measures</b>	
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<b>5.1</b>	<b>Extinguishing media</b>
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	Suitable extinguishing media:	Small fire - water spray, dry powder, CO2 Large fire - water spray or alcohol resistant foam
	Unsuitable extinguishing media:	No information available

<b>5.2</b>	<b>Special hazards arising from the substance or mixture</b>
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	Hazardous combustion products:	Carbon monoxide (CO)
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<b>5.3</b>	<b>Advice for firefighters</b>
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	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.
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<b>5.4</b>	<b>Additional information</b>
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	Do not contaminate the environment with extinguishing media.
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Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

<b>SECTION 6. Accidental release measures</b>	
6.1	Personal precautions, protective equipment and emergency procedures
6.1.1.	For non-emergency personnel
	Protective equipment: Use personal protective equipment (see Section 8).
	Accident prevention methods: Evacuate members of all non-essential personnel and those members without protective equipment. 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.	Bundling, 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
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

<b>SECTION 7. Handling and storage</b>	
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.

Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

Other measures:	-		
<b>7.1.2.</b>	<b>Advice on general occupational hygiene:</b>		
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.		
<b>7.2</b>	<b>Conditions for safe storage, including any incompatibilities</b>		
	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.	
	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).	
<b>7.3</b>	<b>Specific end use(s)</b>		
	Recommendations:	-	
	Industrial sector specific solutions:	-	

<b>SECTION 8. Exposure controls/personal protection</b>				
<b>8.1</b>	<b>Control parameters</b>			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
Acetone	67-64-1	500	1210	No information available
Substance name:	-			
EC No:	-	CAS No:	-	
<b>DNEL</b>				
<b>Industrial</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	1210 mg/m <sup>3</sup> (acetone)
Dermal	-	-	-	186 mg/kg (acetone)

Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

Critical physical parameters: solubility, flammability, corrosivity:	-
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<b>Consumer</b>				
<b>Route of exposure:</b>	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	200 mg/m <sup>3</sup> (acetone)	-
Dermal	-	-	62 mg/kg (acetone)	-

<b>PNEC</b>	
Environmental protection target	<b>PNEC</b>
Fresh water	10.6 mg/l (acetone)
Freshwater sediments	30.4 mg/kg (acetone)
Marine water	1.06 mg/l (acetone)
Marine sediments	3.04 mg/kg (acetone)
Food chain	No information available
Microorganisms in sewage treatment	100 mg/l (acetone)
Soil (agricultural)	29.5 mg/kg (acetone)
Air	No information available

8.2	<b>Exposure controls</b>	
8.2.1.	<b>Appropriate engineering controls</b>	
	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.	<b>Personal protection equipment</b>	
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	

Trading name:	<b>ACETONE FOR HISTOLOGY</b>				
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

	Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Full contact: Glove material: butyl rubber Glove thickness: $\geq$ 0.50 mm Time until perforation: > 480 min Splash contact: Glove material: nitrile rubber Glove thickness: 0.4 mm Break through time: 35 min
	Other skin protection:	During every day work use antistatic clothing (EN 13688) 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.
8.2.2.3.	Respiratory protection:	If the concentration level exceeds the GVI values (or because of inadequate ventilation), use a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	<b>Environmental exposure controls</b>	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

**SECTION 9. Physical and chemical properties**

9.1 Information on basic physical and chemical properties

	Value	Method
Physical state:	liquid	Visual inspection
Color:	colourless	Visual inspection
Odour/odour threshold:	acetone like/no information available	No information available
Melting point / freezing point:	-94.7 °C	No information available



Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

Boiling point or initial boiling point and boiling range:	56.1 °C	No information available
Flammability:	Highly flammable	No information available
Lower and upper explosion limit:	2.5 vol % 14.3 vol %	No information available
Flash point:	-17 °C	No information available
Auto-ignition temperature:	465 °C	No information available
Decomposition temperature:	No information available	No information available
pH:	No information available	No information available
Kinematic viscosity:	Dynamic 0.32 mPas (at 20°C)	No information available
Solubility:	with water fully miscible	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	240 hPa	No information available
Density and/or relative density	0.79 g/cm <sup>3</sup> at 20 °C	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
Physical state:	No information available	No information available

9.2	Other information
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**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:	Carbon monoxide.

**SECTION 11. Toxicological information**

11.1 Information on toxicological effects

Acute toxicity:					
Route of exposure:	Method	Species	Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results

Trading name:	<b>ACETONE FOR HISTOLOGY</b>				
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

Oral:	-	rat	LD <sub>50</sub>	-	>2,000 mg/kg (acetone)
Dermal:	-	rat	LD <sub>50</sub>	-	>2,000 mg/kg (acetone)
Inhalation:	-	rat	LD <sub>50</sub>	4 h	20 mg/l (acetone)

**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	may cause drowsiness or dizziness

**Aspiration hazard:** No information available.

**Irritation and corrosion**

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	causes serious eye irritation

**Sensitization**

Skin sensitization:	-
Respiratory sensitization:	-

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

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

**Repeated dose toxicity (subacute, subchronic, chronic)**

	Dose	Exposure time	Species	Method	Evaluation	Note
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Trading name:	<b>ACETONE FOR HISTOLOGY</b>					
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7	

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	-

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Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

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.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
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SECTION 12. Ecological information						
12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	fish	No information available	> 1,000 mg/l (acetone)	-
Crustacea:	EC <sub>50</sub>	48 hours	Daphnia magna	No information available	> 1,000 mg/l (acetone)	-
Algae/aquatic plants	IC <sub>50</sub>	8 days	algae	No information available	> 1,000 mg/l (acetone)	-
Other organisms	-	72 hours	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

Trading name:	<b>ACETONE FOR HISTOLOGY</b>				
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

<b>12.2</b>	<b>Persistence and degradability</b>
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	Abiotic degradation
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	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

	Biodegradation
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% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

<b>12.3</b>	<b>Bioaccumulative potential</b>
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	Octanol-water partition coefficient (log K <sub>ow</sub> )
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Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

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Trading name:	<b>ACETONE FOR HISTOLOGY</b>				
Product code:	AC-X**	Date of compilation:	14 September 2022	Version:	7

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

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

**12.4 Mobility in soil**

Known or predicted distribution in environmental compartments:						
No information available						
Surface tension:						
Value	°C	Concentration	Method	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	information available	No information available	No information available	No information available	-
Water-air	No information available	information available	No information available	No information available	No information available	-
Soil-air	No information available	information available	No information available	No information available	No information available	-

Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

<b>12.5.</b>	<b>Results of PBT and vPvB assessment</b>
	Based on available data, the product does not contain any PBT or vPvB substances.
<b>12.6.</b>	<b>Endocrine disrupting properties</b>
	No known endocrine disrupting properties that affect the environment.
<b>12.7.</b>	<b>Other adverse effects</b>
	No information available
<b>SECTION 13. Disposal considerations</b>	
<b>13.1</b>	<b>Waste treatment methods</b>
<b>13.1.1.</b>	<b>Product/Packaging disposal:</b>
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
<b>13.1.2.</b>	<b>Waste codes/waste designations according to Law:</b>
	No information available
<b>13.1.3.</b>	<b>Waste treatment – relevant information:</b>
	No information available
<b>13.1.4.</b>	<b>Sewage disposal – relevant information:</b>
	Waste must not be disposed of into the sewage system.
<b>13.1.5.</b>	<b>Other disposal recommendations:</b>
	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.
<b>13.1.6.</b>	<b>Relevant Community provisions:</b>
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<b>SECTION 14 TRANSPORT INFORMATION</b>	
	Transporting/shipment by road (ADR)
UN number:	1090

Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

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

Transporting/shipment by rail (RID)

UN number:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)

UN number:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)

UN number:	1090
UN proper shipping name:	Acetone
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:	1090
UN proper shipping name:	Acetone
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-



Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

Further information:	-
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**SECTION 15. Regulatory information**

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>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</p>
15.2	Chemical safety assessment	
	None	

**SECTION 16. Other information**

16.1	Indication of changes:	-
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Trading name:	<b>ACETONE FOR HISTOLOGY</b>			
Product code:	AC-X**	Date of compilation:	14 September 2022	Version: 7

16.2	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>								
16.3.	Key literature references and source of data:	-								
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)									
	Classification	Classification procedure								
	-	-								
16.5.	Relevant H statements (number and full text)									
	<table style="border: none;"> <tr><td style="padding-right: 10px;">225</td><td style="padding-right: 10px;">Highly flammable liquid and vapor.</td></tr> <tr><td style="padding-right: 10px;">H: 319</td><td style="padding-right: 10px;">Causes serious eye irritation.</td></tr> <tr><td style="padding-right: 10px;">336</td><td style="padding-right: 10px;">May cause drowsiness or dizziness.</td></tr> <tr><td style="padding-right: 10px;">EUH066</td><td style="padding-right: 10px;">Repeated exposure may cause skin dryness or cracking.</td></tr> </table>	225	Highly flammable liquid and vapor.	H: 319	Causes serious eye irritation.	336	May cause drowsiness or dizziness.	EUH066	Repeated exposure may cause skin dryness or cracking.	
225	Highly flammable liquid and vapor.									
H: 319	Causes serious eye irritation.									
336	May cause drowsiness or dizziness.									
EUH066	Repeated exposure may cause skin dryness or cracking.									
16.6.	Training advice:	-								
16.7.	Further information:	-								



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

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>		
1.1.	Product identifier	
	Trade name:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION
	Chemical name:	-
	Catalogue number:	G4-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Sudan Black B kit.
	Uses advised against:	Only the identified uses are advised
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device and there is no reason to use it for other purposes
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

<b>SECTION 2. HAZARDS IDENTIFICATION</b>		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statement*:
	Acute Tox. 4	H302
	Skin Sens. 1	H317
	Acute Tox. 4	H332
	Resp. Sens. 1	H334
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	GLUTARALDEHYDE, 4% BUFFERED SOLUTION
	Identification number:	-

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>			
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

Authorisation number:	-	
Hazard pictograms:	 GHS07	 GHS08
Signal word:	Danger	
Hazard statement:	H302 Harmful if swallowed. H317 May cause an allergic skin reaction. H332 Harmful if inhaled. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
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. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
Supplemental hazard information (EU):	-	

<b>2.3. Other hazards</b>
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**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)
111-30-8/ 203-856-5/ 605-022-00-X	-	4- 5 %	glutaraldehyde	Acute. Tox. 3; H331 Acute Tox. 3; H301 Skin Corr. 1B; H314 Resp. Sens. 1; H334 Skin Sens. 1; H317 Aquatic Acute 1; H400

**SECTION 4. First aid measures**

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

<b>4.1.</b>	<b>Description of first aid measures</b>	
	General notes:	Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident. Immediately remove any clothing soiled by the product.
	Following inhalation:	Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness place patient stably in side position for transportation.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap and rinse thoroughly. If symptoms persist, consult a doctor.
	Following eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
	Following ingestion:	DO NOT induce vomiting. If symptoms persist, consult a doctor.
	Self-protection of the first aider	Avoid direct contact with the chemical; use appropriate protective equipment described in Section 8.
<b>4.2.</b>	<b>Most important symptoms and effects, both acute and delayed</b>	
	Following inhalation:	High concentration vapor inhalation may cause headache, dizziness, difficult breathing and unconsciousness.
	Following skin contact:	Causes skin irritation, redness, swelling. Prolonged or repeated contact causes defatting and dry skin.
	Following eye contact:	Vapors irritate eyes. Splashing may cause irritation and redness.
	Following ingestion:	Nausea, vomiting (danger of aspiration), diarrhoea. Aspiration may cause headache, vertigo, nausea, dazed feeling-unconsciousness/coma, possible hypothermia, reactions to the heart/circulatory system such as vasodilation (flush), hypotension, arrhythmia (possible ventricular fibrillation through cardiac sensitization), danger of central respiratory paralysis or of cardiac arrest; functional disturbance to the liver and kidneys and persistent disturbance to the CNS as sequelae.
<b>4.3.</b>	<b>Indication of any immediate medical attention and special treatment needed</b>	
	No further relevant information available.	

<b>SECTION 5. Firefighting measures</b>		
<b>5.1.</b>	<b>Extinguishing media</b>	
	Suitable extinguishing media:	CO <sub>2</sub> , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
	Unsuitable extinguishing media:	water with full jet
<b>5.2.</b>	<b>Special hazards arising from the substance or mixture</b>	
	Hazardous by products of fire:	Formation of toxic gases is possible during heating or in case of fire.
<b>5.3.</b>	<b>Advice for firefighters</b>	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

5.4.	Additional information
	Collect contaminated firefighting water separately. Do not contaminate the environment with extinguishing media.

**SECTION 6. Accidental release measures**

6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8). Keep unprotected persons away.
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Do not breathe in vapor, ensure adequate ventilation and avoid contact with skin and eyes. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Do not use tools that may cause sparks.
6.4.	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for ,disposal information.	

**SECTION 7. Handling and storage**

7.1.	Precautions for safe handling
7.1.1.	Protection measures

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>			
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of heat and ignition. Carry out measures for preventing static electricity.
Measures to prevent aerosol and dust generation:	Secure proper ventilation.
Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
Other measures:	-
<b>7.1.2.</b>	<b>Advice on general occupational hygiene:</b>
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.
<b>7.2.</b>	<b>Conditions for safe storage, including any incompatibilities</b>
Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
Packaging materials:	Manufacturer's original packaging.
Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
<b>7.3.</b>	<b>Specific end use(s)</b>
Recommendations:	-
Industrial sector specific solutions:	-

<b>SECTION 8. Exposure controls/personal protection</b>				
<b>8.1.</b>	<b>Control parameters</b>			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
Glutaraldehyde	111-30-8	0.05/0.05	0.2/0.2	-
Substance:	-			
EC No:	-	CAS No:	-	
<b>DNEL</b>				

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

<b>Industrial</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-
Critical physical parameters: solubility, flammability, corrosivity:			-	

<b>Consumer</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

<b>PNEC</b>	
Environmental protection target	<b>PNEC</b>
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

<b>8.2.</b>	<b>Exposure controls</b>	
<b>8.2.1.</b>	<b>Appropriate engineering controls</b>	
	Substance/mixture related measures to prevent exposure during identified uses:	Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
<b>8.2.2.</b>	<b>Personal protection equipment:</b>	



Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

8.2.2.1.	Eye and face protection:	Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU)
8.2.2.2.	Skin protection	
	Hand protection:	<p>Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.</p> <p>Full contact:</p> <p style="padding-left: 40px;">Glove material: Viton  Glove thickness: 0.7 mm  Break through time: 480 min</p> <p>Splash contact:</p> <p style="padding-left: 40px;">Glove material: Nitrile rubber  Glove thickness: 0.4 mm  Break through time: 35 min</p>
	Other skin protection:	Complete suit protecting against chemicals, flame retardant antistatic protective clothing (EN 13688). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
8.2.2.3.	Respiratory protection:	Where risk assessment shows air-purifying respirators are appropriate use type ABEK (EN 14387) respirator cartridges as a backup to engine protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as CEN (EU).
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

**SECTION 9. Physical and chemical properties**

9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	Colour:	colourless	No information available
	Odour/odour threshold:	No information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
	-		

<b>SECTION 10.: Stability and reactivity</b>		
10.1.	Reactivity:	No relevant information available.
10.2.	Chemical stability:	The product is chemically stable under recommended storage conditions.
10.3.	Possibility of hazardous reactions:	No dangerous reactions known.
10.4.	Conditions to avoid:	Sources of heat, flames and sparks.
10.5.	Incompatible materials:	Strong oxidizing agents.
10.6.	Hazardous decomposition products:	Carbon monoxide.

<b>SECTION 11. Toxicological information</b>					
11.1. Information on toxicological effects					
Acute toxicity:					
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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

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

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

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

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Eye exposure:	Vapors irritate eyes. Splashing may cause irritation and redness, lacrimation, pain, swelling, blurred vision, photophobia.
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Repeated dose toxicity (subacute, subchronic, chronic)						
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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

Specific target organ toxicity - repeated exposure (STOT-RE):			
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	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	No information available
Mutagenicity <i>in-vitro</i> :	No information available
Genotoxicity:	No information available
Mutagenicity <i>in-vivo</i> :	No information available
Germ cell mutagenicity :	No information available
Reproductive toxicity:	No information available
Summary of evaluation of the CMR properties:	No information available

11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
	-

<b>SECTION 12. Ecological information</b>						
12.1. Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	-	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	-	-
Algae/aquatic plants:	IC <sub>50</sub>	72 hours	No information available	No information available	-	-
Other organisms:	-	-	-	-	-	-

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants:	IC <sub>50</sub>	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	-

**12.3. Bioaccumulative potential**

Octanol-water partition coefficient (log Kow)

Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

Bioconcentration Factor (BCF)

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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 <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (Daphnia)	EC <sub>50</sub>	No information available	No information available	No information available	No information available	-

**12.4. Mobility in soil**

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

Value	°C	Concentration	Method	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**

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>				
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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<b>12.6.</b>	<b>Endocrine disrupting properties</b>
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	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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<b>12.7.</b>	<b>Other adverse effects</b>
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	No information available
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<b>SECTION 13. Disposal considerations</b>	
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<b>13.1.</b>	<b>Waste processing methods</b>
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<b>13.1.1.</b>	<b>Product/Packaging disposal:</b>
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	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
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<b>13.1.2.</b>	<b>Waste codes/waste designations according to Low:</b>
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	Disposal must be made according to official regulations.
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<b>13.1.3.</b>	<b>Waste tretment – relevant information</b>
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	No information available
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<b>13.1.4.</b>	<b>Sewage disposal – relevant information:</b>
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	Waste must not be disposed of into the sewage system.
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<b>13.1.5.</b>	<b>Other disposal recommendations:</b>
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	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
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<b>13.1.6.</b>	<b>Relevant Community provisions:</b>
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<b>SECTION 14. Transport information</b>	
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	Transporting/shipment by road (ADR)
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Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>			
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

Transporting/shipment by rail (RID)

UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

Transporting/shipment by inland waterways (ADN)

UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)

UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk condition in accordance with Annex II. of MARPOL 73/78 and IBC Codex:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)

UN number:	3334
UN proper shipping name:	Aviation regulated liquid, n.o.s. (Glutaraldehyde)
Transport hazard class(es):	9
Packing group:	III
Environmental hazards:	-

Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>			
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

Special precautions for user:	-
Further information:	-

**SECTION 15. Regulatory information**

15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorisation and/or restrictions on use	
	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>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</p>
15.2.	Chemical safety assessment	
	None	

**SECTION 16. Other information**

16.1.	Indication of changes:	-
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Trade name:	<b>GLUTARALDEHYDE, 4% BUFFERED SOLUTION</b>			
Product code:	G4-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

16.2.	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H:	<p>H301 Toxic if swallowed.</p> <p>H302 Harmful if swallowed.</p> <p>H314 Causes severe skin burns and eye damage.</p> <p>H317 May cause an allergic skin reaction.</p> <p>H331 Toxic if inhaled.</p> <p>H332 Harmful if inhaled</p> <p>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled</p> <p>H400 Very toxic to aquatic life.</p>
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packaging of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

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

Trading name:	<b>HEMATOXYLIN G3</b>			
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version: 7

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

1.1.	Product identifier		
	Trading name:	HEMATOXYLIN G3	
	Chemical name:	-	
	Catalogue number:	HEMG3-OT-X**	
1.2.	Relevant identified uses of the substance or mixture and uses advised against		
	Uses:	Hematoxylin according to Gill 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:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>	
	National contact:	-	
1.4.	Emergency telephone number		
	National Protection and Rescue Directorate:	112	
	Medical information:	+385 1 2348 342	
	Other information:	-	

**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*:	
	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 G3	
	Identification number:	-	
	Authorization no.:	-	

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

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.
Supplemental hazard information (EU):	-

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

**SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS**

CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
107-21-1/ 203-473-3/ 603-027-00-1	01-2119456816- 28-xxxx	25 - 45 %	ethylene glycol	Acute Tox. 4, H302

**SECTION 4 FIRST AID MEASURES**

4.1.	<b>Description of first aid measures</b>
	<p>General notes:</p> <p align="center">-</p>
	<p>Following inhalation:</p> <p>Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.</p>
	<p>Following skin contact:</p> <p>Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.</p>
	<p>Following eye contact:</p> <p>Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.</p>

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

	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.
<b>4.2.</b>	<b>Most important symptoms and effects, both acute and delayed</b>	
	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. If the symptoms persist, immediately call a physician.
	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.
<b>4.3.</b>	<b>Indication of any immediate medical attention and special treatment needed</b>	
	-	

**SECTION 5 FIREFIGHTING MEASURES**

<b>5.1.</b>	<b>Extinguishing media</b>	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO <sub>2</sub> Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	water jet
<b>5.2.</b>	<b>Special hazards arising from the substance or mixture</b>	
	Hazardous combustion products:	No information available
<b>5.3.</b>	<b>Advice for firefighters</b>	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
<b>5.4.</b>	<b>Additional information</b>	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

**SECTION 6 ACCIDENTAL RELEASE MEASURES**

<b>6.1.</b>	<b>Personal precautions, protective equipment and emergency procedures</b>	
<b>6.1.1.</b>	<b>For non-emergency personnel</b>	
	Protective equipment:	Use personal protective equipment (see Section 8).

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

	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.
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	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

### 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	

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

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).
<b>7.3. Specific end use(s)</b>	
Recommendations:	-
Industrial sector specific solutions:	-

<b>SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION</b>				
<b>8.1. Control parameters</b>				
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m <sup>3</sup>	
Ethylene glycol	107-21-1	20/40	52/104	No information available
Substance name:	-			
EC No:	-	CAS No:	-	
<b>DNEL</b>				
<b>Industrial</b>				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	35 mg/ kg (ethylene glycol)	
Dermal	-	-	-	106 mg/kg (ethylene glycol)
Critical physical parameters: solubility, flammability, corrosivity:			-	
<b>Consumer</b>				



Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	7 mg/kg (ethylene glycol)	-
Dermal	-	-	-	53 mg/kg (ethylene glycol)

**PNEC**

Environmental protection target	PNEC
Fresh water	10 mg/l (ethylene glycol)
Freshwater sediments	37 mg/kg (ethylene glycol)
Marine water	1 mg/l (ethylene glycol)
Marine sediments	3.7 mg/kg (ethylene glycol)
Food chain	No information available
Microorganisms in sewage treatment	199.5 mg/l (ethylene glycol)
Soil (agricultural)	1.53 mg/kg (ethylene glycol)
Air	No information available

**8.2. Exposure controls**

**8.2.1. Engineering measures**

Substance/mixture related measures to prevent exposure during identified uses:	Use 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 standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.11 mm Break through time: >480 min

Trading name:	<b>HEMATOXYLIN G3</b>			
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version: 7

	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:	dark red	No information available
	Odour/odour threshold:	no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	No information available	No information available
	Relative vapour density:	No information available	No information available

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

Particle characteristics:	No information available	No information available
9.2. Other information		
-		

**SECTION 10 STABILITY AND REACTIVITY**

10.1. Reactivity:	See subsections 10.3 through 10.5.
10.2. Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3. Possibility of hazardous reactions:	With strong oxidants, sodium-hydroxide, sulfuric acid, aluminum.
10.4. Conditions to avoid:	Sources of heat, sparks, and ignition.
10.5. Incompatible materials:	Aluminum.
10.6. Hazardous decomposition products:	No information available.

**SECTION 11 TOXICOLOGICAL INFORMATION**

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008					
Acute toxicity:					
Route of exposure:	Method	Species	Effective dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral exposure:	anhydrous (ECHA)	rabbit	LD <sub>50</sub>	-	7.712 mg/kg (ethylene glycol)
Dermal exposure:	anhydrous (ECHA)	rat	LD <sub>50</sub>	-	>3.500mg/kg (ethylene glycol)
Inhalation exposure:	No information available	-	LC <sub>50</sub>	-	-
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects	Target organ	Note		
Oral exposure:	No information available	No information available	-		
Dermal exposure:	No information available	No information available	-		
Inhalation exposure:	No information available	No information available	-		
Respiratory irritation:	No information available				
Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

Skin irritation:	-	rabbit	-	-	Slight irritation (ethylene glycol)
Eye irritation:	24 h	rabbit	-	-	Slight irritation (ethylene glycol)

Sensitization
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Dermal exposure:	No information available
Inhalation exposure:	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:	Causes serious eye damage

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	-

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

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

Summary of evaluation of the CMR properties:	-
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11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
	-

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

**SECTION 12 ECOLOGICAL INFORMATION:**

**12.1. Toxicity**

Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	Fish	No information available	72.860 mg/l (ethylene glycol)	-
Crustacea:	EC <sub>50</sub>	48 hours	water flea	No information available	>100 mg/l (ethylene glycol)	-
Algae/aquatic plants	IC <sub>50</sub>	8 days	algae	No information available	6.500-13.000 mg/l (ethylene glycol)	-
Microorganisms	LC <sub>50</sub>	72 hours	-	-	-	-
Chronic toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	No information available	No information available	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC <sub>50</sub>	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:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

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**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)

Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

Chronic ecotoxicity

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea ( <i>Daphnia</i> )	EC <sub>50</sub>	No information available	No information available	No information available	No information available	-

**12.4. Mobility in soil**

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

Value	°C	Concentration	Method	Note
No information available	No information available	No information available	No information available	-

Trading name:	<b>HEMATOXYLIN G3</b>				
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version:	7

Adsorption / desorption						
Transport	A/D coefficient Henry's constant		log Kow	Evaporation rate	Method	Note
Soil-water	No information available	information available	No information available	No information available	No information available	-
Water-air	No information available	information available	No information available	No information available	No information available	-
Soil-air	No information available	information available	No information available	No information available	No information available	-

**12.5. Results of PBT and vPvB assessment**  
 Based on available data, the product does not contain any PBT or vPvB substances.

**12.6. Endocrine disrupting properties**  
 No known endocrine disrupting properties that affect the environment.

**12.7. Other adverse effects**  
 No adverse effects are expected.

**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.



Trading name:	<b>HEMATOXYLIN G3</b>			
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version: 7

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.
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:	-

Trading name:	<b>HEMATOXYLIN G3</b>			
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version: 7

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:	-
Restrictions:	-
Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
National legislation:	<p>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</p>

Trading name:	<b>HEMATOXYLIN G3</b>			
Product code:	HEMG3-OT-X**	Revision date:	03 April 2023	Version: 7

15.2.	Chemical safety assessment
	None

**SECTION 16 Other information**

16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H: 302	Harmful if swallowed.
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

**ANNEX:**  
**EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT**

-

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

### SECTION 1: Identification of the substance/mixture and of the company/undertaking




1.1	Product identifier	
	Trading name:	SUDAN BLACK B REAGENT
	Chemical name:	-
	Catalogue number:	SBB-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in hematology, used with Sudan Black B 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:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

### 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
	Acute Tox. 4	H302
	Acute Tox. 4	H312
	Acute Tox. 4	H332
	Skin Irr. 2	H315
	Eye Irr. 2	H319
	Muta. 2	H341
	STOT RE 2	H373
2.1.2.	Additional information	
	-	

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

\*For full text of Hazard- and EU Hazard-statements: see SECTION 16

2.2 Label elements	
Product identification:	SUDAN BLACK B REAGENT
Identification number:	-
Authorization number:	-
Hazard pictograms:	 <p>GHS02</p>  <p>GHS07</p>  <p>GHS08</p>
Signal word:	Danger
Hazard statements:	<p>H225 Highly flammable liquid and vapor.</p> <p>H302+H312+H332 Harmful if swallowed, in contact with skin and if inhaled.</p> <p>H315 Causes skin irritation</p> <p>H319 Causes serious eye irritation</p> <p>H341 Suspected of causing genetic defects.</p> <p>H373 May cause damage to organs through prolonged or repeated exposure.</p>
Precautionary statements:	<p>P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke.</p> <p>P280 Wear protective gloves/protective clothing/eye/protection/face protection.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of water and soap.</p> <p>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.</p>

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610- 43-xxxx	50 - 70 %	ethanol	Flam. Liq. 2; H225
108-95-2/ 203-632-7/ 604-001-00-2	01-2119471329- 32-xxxx	4 - 5 %	phenol	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Skin Corr. 1B; H314 Muta. 2; H341 STOT SE 2; H373

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 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	

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	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	
	-	

<b>SECTION 5. Firefighting measures</b>		
5.1	Extinguishing media	
	Suitable extinguishing media:	Water, foam, dry powder, CO <sub>2</sub>
	Unsuitable extinguishing media:	No information available
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Mixture with combustible ingredients. Forms explosive mixtures with air at elevated temperatures. Development of hazardous combustion gases or vapours possible in the event of fire. Vapours are heavier than air and may spread along floors.
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.	

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

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	Do not let product enter drains. Risk of explosion.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Cover drains. Collect, bind, and pump off spills.
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.	

<b>SECTION 7. Handling and storage</b>		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge. 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.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.



Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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).
<b>7.3 Specific end use(s)</b>	
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 <sup>3</sup>	
Ethanol	64-17-5	1000/-	1900/-	-
Phenol	108-95-2	2/4	8/16	120 mg/g of creatinine (0.14 mol/mol of creatinine), end of shift, urinary excretion

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	1900 mg/ m <sup>3</sup> (ethanol)	-	-	380 mg/m <sup>3</sup> (ethanol) 8 mg/m <sup>3</sup> (phenol)
Dermal	-	-	-	343 mg/kg (ethanol) 1.23 mg/kg (phenol)

Critical physical parameters: solubility, flammability, corrosivity: -

**Consumer**

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	87 mg/kg (ethanol) 0.5 mg/kg (phenol)

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Inhalation	950 mg/ m <sup>3</sup> (ethanol)	-	-	114 mg/m <sup>3</sup> (ethanol) 0.452 mg/ m <sup>3</sup> (phenol)
Dermal	-	-	-	206 mg/kg (ethanol) 0.5 mg/kg (phenol)

<b>PNEC</b>	
Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol) 0.0077 mg/l (phenol)
Freshwater sediments	3.6 mg/kg (ethanol) 0.09125 mg/kg (phenol)
Marine water	0.79 mg/l (ethanol) 0.00077 mg/l (phenol)
Marine sediments	2.9 mg/kg (ethanol) 0.00915 mg/kg (phenol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	2.1 mg/l (phenol)
Soil (agricultural)	0.63 mg/kg (ethanol) 0.136 mg/kg (phenol)
Air	no information available

<b>8.2</b>	<b>Exposure controls</b>	
<b>8.2.1.</b>	<b>Appropriate engineering controls</b>	
	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.
<b>8.2.2.</b>	<b>Personal protection equipment</b>	
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	

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	Hand protection:	<p>The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374.</p> <p>Full contact:</p> <p style="padding-left: 20px;">Glove material: butyl rubber          Glove thickness: 0.70 mm          Break through time: &gt; 480 min</p> <p>Splash contact:</p> <p style="padding-left: 20px;">Gloves material: nitrile rubber          Glove thickness: 0.40 mm          Break through time: &gt; 120 min</p>
	Other skin protection:	<p>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.</p>
8.2.2.3.	Respiratory protection:	<p>Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point &gt;65°C) according to EN 14387) used when concentration levels exceed GVI.</p>
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:	black	No information available
	Odour/odour threshold:	mild phenol like/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	21°C	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

### SECTION 10. Stability and reactivity

10.1	Reactivity:	See subsections 10.3 through 10.5.
10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3	Possibility of hazardous reactions:	No information available
10.4	Conditions to avoid:	Heating.
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 <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mix</sub>	Exposure time	Results
Oral:	-	rat	LD <sub>50</sub>	-	10.470 mg/kg (ethanol)
Dermal:	-	rat	LD <sub>50</sub>	-	660 mg/kg (phenol)
Inhalation:	-	rat	LC <sub>50</sub>	4 h	124.7 mg/l (ethanol)



Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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)

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.

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
<b>11.2 Practical experiences:</b>		
	Classification observations:	No information available
	Other observations:	No information available
<b>11.3 General notes:</b>		
	-	

<b>SECTION 12. Ecological information</b>						
12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	Leuciscus idus (Golden orfe; ethanol) Oncorhynchus mykiss (rainbow trout; phenol)	-	-	8.140 mg/l (ethanol) 5.0 mg/l (phenol)
Crustacea:	EC <sub>50</sub>	48 hours	Daphnia magna (Water flea)	-	-	7.800 mg/l (ethanol) 3.1 mg/l (phenol)
Algae/aquatic plants	IC <sub>50</sub>	7 days	green algae	-	-	5.000 mg/l (ethanol) 61.1 mg/l (phenol)
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	No information available	-	-	-
Crustacea:	EC <sub>50</sub>	48 hours	No information available	-	-	-
Algae/aquatic plants	IC <sub>50</sub>	72 hours	No information available	-	-	-
Other organisms	-	-	-	-	-	-
12.2 Persistence and degradability						

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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
94% (ethanol)	No information available	OECD 301E	No information available	readily biodegradable
85% (phenol)	14 days	OECD 301C	No information available	readily biodegradable

**12.3 Bioaccumulative potential**

Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
-0,31 (ethanol)	-	-	-	experimental	-	bioaccumulation is not expected
1.47 (phenol)	-	-	30 °C	ECHA	-	bioaccumulation is not expected

**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



Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Chronic toxicity on fish	LC <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea ( <i>Daphnia</i> )	EC <sub>50</sub>	No information available	No information available	No information available	No information available	-

**12.4 Mobility in soil**

Known or predicted distribution in environmental compartments:						
No information available						
Surface tension:						
	Value	°C	Concentration	Method	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**

Based on available data, the product does not contain any PBT or vPvB substances.

**12.6. Endocrine disrupting properties**

Based on available data, does not contain endocrine disruptors.

**12.7. Other adverse effects**

No further relevant information available.

**SECTION 13. Disposal considerations**

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

<b>13.1</b>	<b>Waste treatment methods</b>
<b>13.1.1.</b>	<b>Product/Packaging disposal:</b>
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
<b>13.1.2.</b>	<b>Waste codes/waste designations according to Law:</b>
	15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances
<b>13.1.3.</b>	<b>Waste treatment – relevant information:</b>
	No information available
<b>13.1.4.</b>	<b>Sewage disposal – relevant information:</b>
	Waste must not be disposed of into the sewage system.
<b>13.1.5.</b>	<b>Other disposal recommendations:</b>
	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.
<b>13.1.6.</b>	<b>Relevant Community provisions:</b>
	Disposal must be made according to official regulations.

**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

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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

<b>SECTION 15. Regulatory information</b>	
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>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</p>
15.2	Chemical safety assessment	
	None	

<b>SECTION 16. Other information</b>		
16.1	Indication of changes:	-
16.2	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	-

Trading name:	<b>SUDAN BLACK B REAGENT</b>				
Product code:	SBB-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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)		
	H225	Highly flammable liquid and vapor.	
	H301	Toxic if swallowed.	
	H302	Harmful if swallowed.	
H:	H311	Toxic in contact with skin.	
	H312	Harmful in contact with skin.	
	H314	Causes severe skin burns and eye damage.	
	H315	Causes skin irritation.	
	H319	Causes serious eye irritation.	
	H331	Toxic if inhaled.	
	H332	Harmful if inhaled.	
	H341	Suspected of causing genetic defects.	
	H373	May cause damage to organs through prolonged or repeated exposure.	
16.6.	Training advice:	-	
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>	

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