

GROCOTT KIT, STABILIZED

The kit contains:

Borax, solution

Fast Green F.C.F. contrast reagent

Gold chloride, 0.6% solution

Methenamine, solution

Periodic acid, 1% solution

Silver nitrate, stabilized solution


Sodium thiosulfate, 2% solution

Trade name:	BORAX, SOLUTION		
Product code:	BO-OT-X**	Date of compilation:	14 November 2022
		Version:	3

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	BORAX, SOLUTION
	Chemical name:	-
	Catalogue number:	BM-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Grocott kit, stabilized and P.A.S.M. Jones kit, stabilized.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone numbers	
	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 statement*:
	Repr. 1B	H360FD
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	BORAX, SOLUTION
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	
	GHS08
Signal word:	Danger
Hazard statement:	H360FD May damage fertility. May damage the unborn child.
Precautionary statements:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P308+P313 IF exposed or concerned: Get medical advice/attention.
Supplemental hazard information (EU):	-
2.3. Other hazards	
	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. Included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH).

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)
1330-43-4/ 215-540-4/ 005-011-00-4	-	4 - 5%	disodium tetraborate	Eye Irr. 2; H319 Repr. 1B; H360FD

SECTION 4. First aid measures	
4.1.	Description of first aid measures
General notes:	Show this material safety data sheet to the doctor in attendance.
Following inhalation:	After inhalation: fresh air. Call in physician.
Following skin contact:	After inhalation: fresh air. Call in physician.
Following eye contact:	After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.
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.
4.2.	Most important symptoms and effects, both acute and delayed

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	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 diarrhea, abdominal cramps, and erythematous lesions on the skin and mucous membranes. Other symptoms include: circulatory collapse, tachycardia, cyanosis, delirium, convulsions, and coma.
4.3.	Indication of any immediate medical attention and special treatment needed	
	No further relevant information available.	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	CO ₂ , dry powder, water foam.
	Unsuitable extinguishing media:	For this substance/mixture no limitations of extinguishing agents are given.
5.2.	Special hazards arising from the substance or mixture	
	Hazardous by products of fire:	Formation of toxic gases is possible during heating or in case of fire.
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4.	Additional information	
	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).	

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6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, 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	
	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:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.

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Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3. Specific end use(s)	
Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	-

Substance: -

EC No: - CAS No: -

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

PNEC

Environmental protection target	PNEC
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Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
	Substance/mixture related measures to prevent exposure during identified uses:	Use 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:	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	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.
	Hand protection:	<p>Full contact:</p> <p>Glove material: Viton Glove thickness: 0.7 mm Break through time: 480 min</p> <p>Splash contact:</p> <p>Glove material: Nitrile rubber Glove thickness: 0.4 mm Break through time: 35 min</p>

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	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
	Colour:	colourless	No information available
	Odour/odour threshold:	no odour/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

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	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2.	Other information		
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SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	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:	No information available
10.5.	Incompatible materials:	No information available
10.6.	Hazardous decomposition products:	No information available

SECTION 11. Toxicological information					
11.1. Information on toxicological effects					
Acute toxicity:					
Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral:	OECD Test Guideline 401	rat	LD ₅₀	No information available	>2.500 mg/kg (disodium tetraborate)
Dermal:	No information available	rabbit	LD ₅₀	No information available	>2.000 mg/kg (disodium tetraborate)
Inhalation:	No information available	rat	LC ₅₀	4 h	>2.12 mg/l (disodium tetraborate)
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	Respiratory system	-		

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Aspiration hazard:	-
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Irritation and corrosion					
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	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-

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

Symptoms related to physical, chemical, and toxicological properties	
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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.
Eye exposure:	Vapors irritate eyes. Splashing may cause irritation and redness, lacrimation, pain, swelling, blurred vision, photophobia.

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	-

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

Specific target organ toxicity - repeated exposure (STOT-RE):						
		Specific effects		Target organ		Note

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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	-

11. CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)

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:	May damage the unborn child. May damage fertility.

Summary of evaluation of the CMR properties:	No information available
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11.2. Information on other hazards:

11.2.1. Endocrine disrupting properties:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

11.2.2. Other information:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12. Ecological information

12.1. Toxicity

Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
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Trade name:	BORAX, SOLUTION					
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Fish	LC ₅₀	96 hours	-	No information available	-	-
Crustacea:	EC ₅₀	48 hours	-	No information available	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	No information available	-	-
Other organisms:	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	-	-
Crustacea:	EC ₅₀	48 hours	-	-	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	-	-	-
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	-

12.3. Bioaccumulative potential

Trade name:	BORAX, SOLUTION					
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Octanol-water partition coefficient (log Kow)						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	-	-

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

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

12.4. Mobility in soil

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

Adsorption / desorption						
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note	

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Soil-Water	No information available	No information available	No information available	No information available	-
Water-Air	No information available	No information available	No information available	No information available	-
Soil-Air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

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.

12.6. Endocrine disrupting properties

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.

12.7. Other adverse effects

Discharge into the environment must be avoided.

SECTION 13. Disposal considerations

13.1. Waste processing 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 Low:

Disposal must be made according to official regulations.

13.1.3. Waste treatment – relevant information

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

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

13.1.6. Relevant Community provisions:
 Disposal must be made according to official regulations.

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:	-
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:	-

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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:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
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>COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	

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National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2. Chemical safety assessment	None

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: 319 360DF	Causes serious eye irritation. May damage fertility. May damage the unborn child.
16.6. Training advice:	-
16.7. Further information:	<p>** "X" in the product code marks different volumes (different packaging of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment

Trade name:	BORAX, SOLUTION				
Product code:	BO-OT-X**	Date of compilation:	14 November 2022	Version:	3

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Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT
	Chemical name:	-
	Catalogue number:	FGKR-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Counterstain used with Grocott staining kit.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	-
	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*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	FAST GREEN F.C.F. CONTRAST REAGENT
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	-

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT			
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version: 4

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

2.3	Other hazards
<p>The product has no other known specific hazards for human or environment.</p> <p>Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.</p> <p>Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.</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)
-	-	-	Contains no hazardous substances	-

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	
	Following inhalation:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT			
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version: 4

	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	water spray, dry powder, CO2 or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	no information available
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. 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).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

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

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

Further information on storage conditions:		Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).		
7.3	Specific end use(s)			
	Recommendations:	-		
	Industrial sector specific solutions:	-		

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	-

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

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

PNEC

Environmental protection target	PNEC
Fresh water	no information available
Freshwater sediments	no information available

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

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

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8.2	Exposure controls
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8.2.1.	Appropriate engineering controls
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	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.

8.2.2.	Personal protection equipment
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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.
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8.2.2.2.	Skin protection
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	Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
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	Other skin protection:	During every day 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.
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8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
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8.2.2.4.	Thermal hazards:	No information available
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8.2.3.	Environmental exposure controls
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Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT			
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version: 4

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

SECTION 10. Stability and reactivity	
10.1	Reactivity: See subsections 10.3 through 10.5.

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT			
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version: 4

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:	No information available
10.5	Incompatible materials:	No information available
10.6	Hazardous decomposition products:	No information available

SECTION 11. Toxicological information

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

Acute toxicity:

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

Irritation and corrosion

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

Sensitization

Skin sensitization:	-
Respiratory sensitization:	-

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

Symptoms related to the physical, chemical and toxicological characteristics						
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Oral exposure:	No information available.
Dermal exposure:	No information available.
Inhalation exposure:	No information available.
Eye exposure:	No information available.

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

Specific target organ toxicity – repeated exposure (STOT RE):			
	Specific effects	Target organ	Note

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT			
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version: 4

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

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
Carcinogenicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
Genotoxicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.

11.2.	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	Based on available data, does not contain endocrine disruptors. -
11.2.2.	Other information:
	-

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	4 days	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

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

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

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12.3	Bioaccumulative potential
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	Octanol-water partition coefficient (log Kow)
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Value	Concentration	pH	°C	Method	Evaluation	Note
-	-	-	-	-	-	-

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

	Chronic ecotoxicity
--	---------------------

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

12.4	Mobility in soil
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	Known or predicted distribution in environmental compartments:
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	No information available
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	Surface tension:
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Value	°C	Concentration	Method	Note
No information available	No information available	No information available	No information available	-

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

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

SECTION 13. Disposal considerations

13.1 Waste treatment methods

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

13.1.2. Waste codes/waste designations according to Law:
 15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3. Waste treatment – relevant information:
 No information available

13.1.4. Sewage disposal – relevant information:

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT			
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version: 4

	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations: Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.
13.1.6.	Relevant Community provisions: -

SECTION 14. Transport information

Transporting/shipment by road (ADR)	
UN number:	Not 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:	-

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

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:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

SECTION 15. Regulatory information	
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -
	Other EU regulations: <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>COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</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)

Trading name:	FAST GREEN F.C.F. CONTRAST REAGENT				
Product code:	FGRK-OT-X**	Date of compilation:	23 Dec 2022	Version:	4

National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
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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: -	-
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

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Trading name:	GOLD CHLORIDE, 0.6% SOLUTION				
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	GOLD CHLORIDE, 0.6% SOLUTION
	Chemical name:	-
	Catalogue number:	ZK06-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Component of many special staining kits.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification		
2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	GOLD CHLORIDE, 0.6% SOLUTION
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	-

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION			
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version: 2

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

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

SECTION 3. Composition/information on ingredients				
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CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
-	-	-	Contains no hazardous substances	-

SECTION 4. First aid measures	
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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	
Following inhalation:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.	

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	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	water spray, dry powder, CO ₂ or alcohol resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	no information available
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.

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Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version: 2

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

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat. Do not use tools that cause sparks. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.

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Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3	Specific end use(s)
	Recommendations: -
	Industrial sector specific solutions: -

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	-

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

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

PNEC

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

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION			
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version: 2

Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	no information available
Air	no information available

8.2	Exposure controls
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8.2.1.	Appropriate engineering controls
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	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.

8.2.2.	Personal protection equipment
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8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
	Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
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
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	Substance/mixture related measures to prevent exposure:	See Section 6
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Trading name:	GOLD CHLORIDE, 0.6% SOLUTION		
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022
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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:	light yellow	No information available
	Odour/odour threshold:	no information available/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

SECTION 10. Stability and reactivity

10.1	Reactivity:	See subsections 10.3 through 10.5.
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Trading name:	GOLD CHLORIDE, 0.6% SOLUTION				
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

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:	No information available
10.5	Incompatible materials:	No information available
10.6	Hazardous decomposition products:	No information available

SECTION 11. Toxicological information

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

Acute toxicity:

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

Irritation and corrosion

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

Sensitization

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

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION				
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

Symptoms related to the physical, chemical and toxicological characteristics						
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Oral exposure:	No information available.
Dermal exposure:	No information available.
Inhalation exposure:	No information available.
Eye exposure:	No information available.

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

Specific target organ toxicity – repeated exposure (STOT RE):			
	Specific effects	Target organ	Note

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION				
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

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

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
Carcinogenicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
Genotoxicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.

11.2	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
11.2.2.	Other information:
	-

SECTION 12. Ecological information

12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION				
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	4 days	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

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

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION			
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version: 2

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12.3 Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

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

Bioconcentration factor (BCF)

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

Chronic ecotoxicity

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

12.4 Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

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

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION				
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

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

12.5 Results of PBT and vPvB assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No further relevant information available.

SECTION 13. Disposal considerations

13.1 Waste treatment methods

13.1.1. Product/Packaging disposal:

Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2. Waste codes/waste designations according to Law:

15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION		
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022
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	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations: Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.
13.1.6.	Relevant Community provisions: Disposal must be made according to official regulations.

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:	-

Trading name:	GOLD CHLORIDE, 0.6% SOLUTION				
Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

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:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

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

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Product code:	ZK06-OT-X**	Date of compilation:	21 Dec 2022	Version:	2

National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment
	None

SECTION 16. Other information

16.1	Indication of changes:	-
16.2	Abbreviations and acronyms:	<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: -	-
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
-

Trade name:	METHENAMINE, SOLUTION		
Product code:	MET-OT-X**	Date of compilation:	14 November 2022
		Version:	4

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trading name:	METHENAMINE, SOLUTION
	Chemical name:	-
	Product code:	MET-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Grocott and P.A.S.M./Jones 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 and there is no reason to use it for other purposes.
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone numbers	
	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 statement*:
	Skin. Sens. 1	H317
2.1.2.	Additional information	
	-	
*For the full text of H and EUH phrases see Section 16.		
2.2.	Label elements	
	Product identification:	METHENAMINE, SOLUTION
	Identification number:	-
	Authorisation number:	-

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

Hazard pictograms:	
	GHS07
Signal word:	Warning
Hazard statement:	H317 May cause an allergic skin reaction.
Precautionary statement:	P280 Wear protective gloves/protective clothing/eye/face protection. P302+P352 IF ON SKIN: Wash with plenty of water and soap. P308 + P313 IF exposed or concerned: Get medical advice/attention.
Supplemental hazard information (EU):	-
2.3.	Other hazards
	No known endocrine disrupting properties. 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)
100-97-0/ 202-905-8/ 612-101-00-2	-	15 - 25 %	methenamine	Flam. Sol. 2; H228 Skin. Sens. 1B; H317

SECTION 4. First aid measures	
4.1.	Description of first aid measures
General notes:	Move out of dangerous area. Show this safety data sheet to the doctor and first responders.
Following inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Get medical advice.
Following skin contact:	Wash off with soap and plenty of water. If irritation occurs and persists: Get medical advice.
Following eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation occurs and persists: Get medical advice.
Following ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water.

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

	Self-protection of the first aider	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following skin contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
4.3.	Indication of any immediate medical attention and special treatment needed	
	Treat symptomatically.	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Use dry chemical, CO ₂ , water spray (FOG) or foam.
	Unsuitable extinguishing media:	Avoid solid water stream as it may scatter and spread fire.
5.2.	Special hazards arising from the substance or mixture	
	Hazardous by products of fire:	Use water spray to cool fire exposed container surfaces and to protect personnel. Thermal decomposition can produce carbon monoxide (highly toxic) and carbon dioxide (an asphyxiant at sufficient concentrations).
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
5.4.	Additional information	
	Heating may cause container cracking due to increase in pressure. Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use suitable personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.
	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).	

Trade name:	METHENAMINE, SOLUTION			
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version: 4

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.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	After removing the product, use water to wash the work space and used materials.
6.3.3.	Other information:	No information available.
6.4.	Reference to other sections	
	-	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Refer to the manufacturer's recommendations.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	-

Substance:	-
EC No:	-
CAS No:	-

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

PNEC

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
	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.
8.2.2.	Personal protection equipment:	
8.2.2.1.	Eye and face protection:	Safety glasses tested and approved under appropriate standards such as EN 166(EU).
8.2.2.2.	Skin protection:	
	Hand protection:	Handle with chemical resistant gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
	Other skin protection:	No specific protective equipment required.
8.2.2.3.	Respiratory protection:	Use when overexposure potential. Improper use of respirators is dangerous.
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:	colourless to light yellow	No information available

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

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

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	Not reactive under normal conditions.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	Contact with incompatible materials and temperature extremes.
10.5.	Incompatible materials:	Strong oxidizers.
10.6.	Hazardous decomposition products:	Does not decompose under normal conditions. During fire, thermal decomposition can produce carbon monoxide (highly toxic) and carbon dioxide (as asphyxiant as sufficient concentrations).

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity:

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

Specific target organ toxicity - single exposure (STOT-SE):

	Specific effects	Target organ	Note
Oral:	No information available	-	-
Dermal:	No information available	-	-
Inhalation:	No information available	-	-

Aspiration hazard:

	-
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Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	No information available	rabbit	-	-	mild skin irritation
Serious irritation to eyes:	No information available	-	-	-	-

Sensitization

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

Symptoms related to physical, chemical, and toxicological properties

Oral exposure:	No known specific symptoms.
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Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

Dermal exposure:	No known specific symptoms. May cause skin irritation.
Inhalation exposure:	No known specific symptoms.
Eye exposure:	No known specific symptoms.

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

	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	No information available
Subacute dermal	No information available	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	No information available
Subchronic oral	No information available	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	No information available
Subchronic inhalation	No information available	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	No information available
Chronic dermal	No information available	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	No information available

Specific target organ toxicity - repeated exposure (STOT-RE):

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	No information available
Subacute dermal	No information available	No information available	No information available

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

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

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)	
Carcinogenicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in-vitro</i> :	Based on available data, the classification criteria are not met.
Genotoxicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in-vivo</i> :	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	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:
	-

SECTION 12. Ecological information	
12.1.	Toxicity

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	-	-
Crustacea:	EC ₅₀	48 hours	-	-	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	-	-	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	-	-
Crustacea:	EC ₅₀	48 hours	-	-	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	-	-	-
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 K_{ow})

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

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

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

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

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

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	-

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

Soil-air	No information available	No information available	No information available	No information available	-
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12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7. Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2. Waste codes/waste designations according to Law:

Disposal must be made according to official regulations.

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.

13.1.6. Relevant Community provisions:

-

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

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:	-
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 according to Annex II of MARPOL73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

Packing group:	-
Environmental hazards:	-
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	
	-	

SECTION 16. Other information

Trade name:	METHENAMINE, SOLUTION				
Product code:	MET-OT-X**	Date of compilation:	14 November 2022	Version:	4

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:	Manufacturer's MSDS file.
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H: 317	May cause an allergic skin reaction.
16.6.	Training advice:	-
16.7.	Further information:	<p>"X" in the product code marks different volumes (different packaging of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment
-

Trading name:	PERIODIC ACID, 1 % SOLUTION		
Product code:	PK1-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:	PERIODIC ACID, 1 % SOLUTION
	Chemical name:	-
	Catalogue number:	PK1-OT-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
	Fax no.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2 HAZARDS INFORMATION		
2.1.	Classification of the substance or mixture	
2.1.1.	Classification (REGULATION (EC) No. 1272/2008 (CLP))	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Classification according to EC Directive Nr. 1272/2008 CLP)	
	Product identification:	PERIODIC ACID, 1 % SOLUTION
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	-

Trading name:	PERIODIC ACID, 1 % SOLUTION			
Product code:	PK1-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

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

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

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

SECTION 4 FIRST AID MEASURES	
-------------------------------------	--

4.1.	Description of first aid measures	
General notes:	-	
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.	
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.	
Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.	
Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.	
Self-protection of the first aider:	Treat symptomatically.	
4.2.	Most important symptoms and effects, both acute and delayed	
Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.	
Following skin contact:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.	

Trading name:	PERIODIC ACID, 1 % SOLUTION				
Product code:	PK1-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

	Following eye contact:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.
	Following ingestion:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5 FIREFIGHTING MEASURES		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	No information available
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
5.4.	Additional information	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

SECTION 6 ACCIDENTAL RELEASE MEASURES		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Wear protective equipment (see Section 8).	
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	

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6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	-	

SECTION 7 HANDLING AN STORAGE

7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	

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Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	No information available

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

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

PNEC

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available

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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 the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3. Environmental exposure controls		
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Trading name:	PERIODIC ACID, 1 % SOLUTION		
Product code:	PK1-OT-X**	Date of compilation:	21 Dec 2022
		Version:	4

9.1. Information on basic physical and chemical properties			
		Value	Method
	Physical state:	liquid	No information available
	Colour:	colourless	No information available
	Odour/odour threshold:	no odor/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2. Other information			
		-	

SECTION 10 STABILITY AND REACTIVITY		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
10.6.	Hazardous decomposition products:	No information available.

SECTION 11 TOXICOLOGICAL INFORMATION

Trading name:	PERIODIC ACID, 1 % SOLUTION			
Product code:	PK1-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008					
Acute toxicity:					
Route of exposure:	Method	Species	Effective dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects	Target organ	Note		
Oral exposure:	No information available	No information available	-		
Dermal exposure:	No information available	No information available	-		
Inhalation exposure:	No information available	No information available	-		
Respiratory irritation: No information available					
Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	rabbit	-	-	-
Eye irritation:	-	rabbit	-	-	-
Sensitization					
Dermal exposure:	No information available				
Inhalation exposure:	No information available				
Symptoms related to the physical, chemical and toxicological characteristics					
Oral exposure:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.				
Dermal exposure:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.				

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Inhalation exposure:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
Eye exposure:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.

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

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

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

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

11.2	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
11.2.2.	Other information:
	-

SECTION 12 ECOLOGICAL INFORMATION:						
12.1.	Toxicity					
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-

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

12.2. Persistence and degradability

Abiotic degradation						
	Degradation half-lives		Method		Evaluation	Note
Marine water	No information available		No information available		No information available	-
Fresh water	No information available		No information available		No information available	-
Air	No information available		No information available		No information available	-
Soil	No information available		No information available		No information available	-

Biodegradation

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

12.3. Bioaccumulative potential

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

Trading name:	PERIODIC ACID, 1 % SOLUTION				
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-	No information available	-	-	No information available	No information available	-
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Bioconcentration factor (BCF)

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

Chronic ecotoxicity

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

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:
 No information available

Surface tension:

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

Adsorption / desorption

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

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Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.6. Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7. Other adverse effects

No information available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2. Waste codes/waste designations according to Law:

No information available

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

Trading name:	PERIODIC ACID, 1 % SOLUTION				
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Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.

13.1.6.	Relevant Community provisions:
	-

SECTION 14 TRANSPORT INFORMATION

Transporting/shipment by road (ADR)

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

Transporting/shipment by rail (RID)

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

Inland waterway transport (ADN)

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

Transporting/shipment by sea (IMDG)

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

Trading name:	PERIODIC ACID, 1 % SOLUTION		
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Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

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

Trading name:	PERIODIC ACID, 1 % SOLUTION			
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None

SECTION 16 Other information		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H:	-
16.6.	Training advice:	-
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.

ANNEX:	
Exposure scenario resulting to Chemical safety assessment	
-	

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
Product code:	SNS-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:	SILVER NITRATE SOLUTION, STABILIZED
	Chemical name:	-
	Catalogue number:	SNS-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with Grocott kit, stabilized and P.A.S.M. /Jones kit, stabilized.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification

2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Aquatic Chronic 3	H412
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	SILVER NITRATE SOLUTION, STABILIZED
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	-

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
Product code:	SNS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

Signal word:	-
Hazard statements:	H412 Harmful to aquatic life with long lasting effects.
Precautionary statements:	P273 Avoid release to the environment. P501 Dispose of contents/container in accordance with local regulations.
Supplemental hazard information (EU):	-
2.3	Other hazards
<p>Endocrine Disrupting Properties: No known endocrine disrupting properties</p> <p>Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.</p>	

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
7761-88-8/ 231-853-9/ 047-001-00-2	-	0.4 – 0.5 %	silver nitrate	Ox. Sol. 2; H272 Skin Corr. 1B; H314 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

SECTION 4. First aid measures	
4.1	Description of first aid measures
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
Following ingestion:	Rinse the oral cavity, drink 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
Product code:	SNS-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:	Danger of gastric perforation.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Water spray, foam, dry powder, CO ₂ or alcohol resistant foam.
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Nitrogen oxides (NO _x). During heating or in case of fire poisonous gases are produced.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3	Methods and material for containment and cleaning up	

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
Product code:	SNS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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.	

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from sources of ignition and heat.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers at temperatures ranging from +2 to +8 °C.
	Packaging materials:	Manufacturer's original packaging. Avoid metal containers.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).

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7.3	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Silver (as Ag)	-	-	0.01	-

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

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

PNEC

Environmental protection target	PNEC
Fresh water	no information available
Freshwater sediments	no information available
Marine water	no information available
Marine sediments	no information available
Food chain	no information available
Microorganisms in sewage treatment	no information available
Soil (agricultural)	no information available

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Air	no information available	
8.2 Exposure controls		
8.2.1. Appropriate engineering controls		
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.
8.2.2. Personal protection equipment		
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2. Skin protection		
	Hand protection:	Protective nitrile gloves, >0.11 mm thick (EN 374).
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 340) and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Not required under normal conditions of use. Use suitable respiratory protective device when high concentrations are present.
8.2.2.4.	Thermal hazards:	No information available
8.2.3. Environmental exposure controls		
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
Product code:	SNS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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

SECTION 10. Stability and reactivity		
10.1	Reactivity:	See subsections 10.3 through 10.5.
10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3	Possibility of hazardous reactions:	No dangerous reactions known.
10.4	Conditions to avoid:	No information available
10.5	Incompatible materials:	No information available
10.6	Hazardous decomposition products:	No information available

SECTION 11. Toxicological information	
11.1	Information on hazard classes as defined in Regulation (EC) No 1272/2008
	Acute toxicity:

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
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Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	No information available	-	No information available	-
Dermal:	-	No information available	-	No information available	-
Inhalation:	-	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: No information available.

Irritation and corrosion

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

SECTION 12. Ecological information						
12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Leuciscus idus (Golden orfe)	-	-	0.011 mg/l (silver nitrate)
Crustacea:	EC ₅₀	48 hours	<i>Daphnia magna</i> (Water flea)	-	-	0.0082 mg/l (silver nitrate)
Algae/aquatic plants	IC ₅₀	4 days	Pseudokirchneriella subcapitata (green algae)	-	-	0.19 mg/l (silver nitrate)
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-

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Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

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

12.3 Bioaccumulative potential

Octanol-water partition coefficient (log K_{ow})

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

Bioconcentration factor (BCF)

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

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
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Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4 Mobility in soil

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

Adsorption / desorption

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

	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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12.6.	Endocrine disrupting properties
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7.	Other adverse effects
	No information available

SECTION 13. Disposal considerations

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

13.1.2.	Waste codes/waste designations according to Law:
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3.	Waste treatment – relevant information:
	No information available

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

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

13.1.6.	Relevant Community provisions:
	-

SECTION 14 TRANSPORT INFORMATION

Transporting/shipment by road (ADR)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-

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Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
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:	Not subject to transport regulations
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Further information:	-

SECTION 15. Regulatory information

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
Product code:	SNS-OT-X**	Date of compilation:	21 Dec 2022	Version:	4

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:	-

Trading name:	SILVER NITRATE SOLUTION, STABILIZED				
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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)	
	272	May intensify fire; oxidiser.
	314	Causes severe skin burns and eye damage.
	H: 400	Very toxic to aquatic life.
	410	Very toxic to aquatic life with long lasting effects.
	412	Harmful to aquatic life with long lasting effects
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:	SODIUM THIOSULFATE, 2% SOLUTION		
Product code:	NT2-OT-X**	Date of compilation:	21 Dec 2022
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SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1.	Product identifier	
	Trading name:	SODIUM THIOSULFATE, 2% SOLUTION
	Chemical name:	-
	Catalogue number:	NT2-OT-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
	Fax no.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification

2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	SODIUM THIOSULFATE, 2% SOLUTION
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	-

Trading name:	SODIUM THIOSULFATE, 2% SOLUTION			
Product code:	NT2-OT-X**	Date of compilation:	21 Dec 2022	Version: 4

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

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

SECTION 3. Composition/information on ingredients				
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CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
7772-98-7/ 231-867-5/ -	-	2 %	sodium thiosulphate	not classified

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

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	Following eye contact:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
	Following ingestion:	According to our findings, chemical, physical and toxicological properties of the substance have not been entirely tested.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	No information available
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
5.4.	Additional information	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Wear protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Sand or clay barriers.

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Product code:	NT2-OT-X**	Date of compilation:	21 Dec 2022
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6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	-	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	
	Recommendations:	-
	Industrial sector specific solutions:	-

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SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	No information available

Substance name: -

EC No: - CAS No: -

DNEL

Industrial

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

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

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

PNEC

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

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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 the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min	
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).	
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.	
8.2.2.4.	Thermal hazards:	No information available	
8.2.3.	Environmental exposure controls		
	Substance/mixture related measures to prevent exposure:	See Section 6	
	Structural measures to prevent exposure:	Use modern equipment.	
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.	
	Technical measures to prevent exposure:	See Section 6	

SECTION 9. Physical and chemical properties

9.1.	Information on basic physical and chemical properties		
		Value	Method

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

SECTION 10. Stability and reactivity

10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available
10.4.	Conditions to avoid:	No information available
10.5.	Incompatible materials:	No information available
10.6.	Hazardous decomposition products:	No information available

SECTION 11. Toxicological information

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

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

Specific target organ toxicity – single exposure (STOT SE):

	Specific effects	Target organ	Note
Oral exposure:	No information available	No information available	-
Dermal exposure:	No information available	No information available	-
Inhalation exposure:	No information available	No information available	-

Respiratory irritation: No information available

Irritation and corrosion

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

Sensitization

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

Symptoms related to the physical, chemical and toxicological characteristics

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

Repeated dose toxicity (subacute, subchronic, chronic)

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	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

Specific target organ toxicity – repeated exposure (STOT RE):

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
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	-

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Chronic inhalation	No information available	No information available	-
CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)			
Carcinogenicity:	Based on available data, the classification criteria are not met.		
Mutagenicity <i>in-vitro</i> :	Based on available data, the classification criteria are not met.		
Genotoxicity:	Based on available data, the classification criteria are not met.		
Mutagenicity <i>in-vivo</i> :	Based on available data, the classification criteria are not met.		
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.		
Reproductive toxicity:	Based on available data, the classification criteria are not met.		
Summary of evaluation of the CMR properties: -			
11.2	Information on other hazards:		
11.2.1.	Endocrine disrupting properties:		
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.		
11.2.2.	Other information:		
	-		

SECTION 12. Ecological information						
12.1. Toxicity						
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-

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

12.2. Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

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

12.3. Bioaccumulative potential

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

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

Bioconcentration factor (BCF)

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

Chronic ecotoxicity

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

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

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

Adsorption / desorption

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

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12.5.	Results of PBT and vPvB assessment
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.6.	Endocrine disrupting properties
	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7.	Other adverse effects
	No information available
SECTION 13. Disposal considerations	
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law:
	No information available
13.1.3.	Waste treatment – relevant information:
	No information available
13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations:
	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:
	-

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SECTION 14. Transport information

Transporting/shipment by road (ADR)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
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:	-

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Special precautions for user:	-
Further information:	-

SECTION 15. Regulatory information

15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<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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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:	-
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
-