

URIGNOST SM KIT

The kit contains:


UriGnost SM reagent

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	24 May 2022	Version:	4

SECTION 1. Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	URIGNOST SM REAGENT
	Chemical name:	-
	Catalogue number:	UGSM-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Modification acc. to <u>S</u> ternheimer- <u>M</u> albin for staining and microscopic analysis of urine sediment.
	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 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 statement*:
	Not identified as hazardous substance.	H226
2.1.2.	Additional information	
	-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2.	Label elements	
	Product identification:	URIGNOST SM REAGENT
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	
	GHS02
Signal word:	Warning
Hazard statement:	H226 Flammable liquid and vapor
Precautionary statements:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P281 Use personal protective equipment as required.
Supplemental hazard information (EU)	-
2.3. Other hazards	-

SECTION 3. Composition/information on ingredients

CAS/EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43-xxxx	<15 %	ethanol	Flam. Liq. 2; H225

SECTION 4. First aid measures

4.1. Description of first aid measures	
General notes:	-
Following inhalation:	Remove person to fresh air. If breathing stops, immediately apply artificial respiration. If breathing difficulties occur, use emergency breathing apparatus. If the symptoms persist, immediately consult a physician.
Following skin contact:	Remove all contaminated clothes using sterile gauze. 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. Do not induce vomiting. 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:	-

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4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3.	Indication of any immediate medical attention and special treatment needed	
	No information available	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Incomplete combustion of the product.
5.3.	Advice for firefighters	
	Firefighters must always use fireproof suit and self-sustaining breathing apparatus with open circle that contains pressurized air in case of fire in closed space.	
5.4.	Additional information	
	Prevent spills and water used for putting out fire from contaminating waterways by enclosing and covering drains.	

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:	

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	Prevent the product from entering the environment; in case it enters environment, it is necessary to prevent the product from reaching waterways, drainage systems and soil. In the case of considerable environment contamination, contact National protection and rescue directorate.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand or clay barriers.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Do not use incompatible materials (see Section 10)
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protective 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.
	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.

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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:	Secure stations for rinsing eyes and showering in the vicinity of work area.
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection				
8.1. Control parameters				
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Ethanol	64-17-5	1000/-	1900/-	-
Substance name:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity:				
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)
PNEC				
Environmental protection target			PNEC	

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Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	No information available

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

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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:	dark purple	No information available
Odour:	ethanol like	No information available
Odour threshold;	No information available	No information available
pH:	6.0 – 7.0	No information available
Melting point / freezing point;	No information available	No information available
Initial boiling point and boiling range:	No information available	No information available
Flash point:	42°C	No information available
Evaporation rate:	No information available	No information available
Flammability (solid, gas):	No information available	No information available
Upper/lower flammability or explosive limits:	No information available	No information available
Vapour pressure:	No information available	No information available
Vapour density:	No information available	No information available
Relative density:		No information available
Bulk density:	No information available	No information available
Solubility(ies):	Soluble in water	No information available
Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
Viscosity:	No information available	No information available
Explosive properties:	No information available	No information available
Oxidising properties:	No information available	No information available

9.2. Other information

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SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	Hazard from strong reactions with: metals, strong acids, strong oxidizers.
10.4.	Conditions to avoid:	Direct sunlight. Sources of heat, sparks, ignition, and low temperature.
10.5.	Incompatible materials:	Metals.
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:	No information available	rat (ethanol)	LD ₅₀	No information available	7.060 mg/kg
-Dermal:	No information available	-	-	No information available	-
Inhalation:	No information available	rat (ethanol)	LC ₅₀	4 h	20.000 mg/l
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects	Target organ	Note		
Oral:	No information available	No information available	-		
Dermal:	No information available	No information available	-		
Inhalation:	No information available	No information available	-		
Aspiration hazard: May cause respiratory irritation.					
Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	No information available

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

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

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Digestive tract irritation (nausea, diarrhea), burns in mouth and digestive tract, hazard of esophagus and stomach perforation.
Dermal exposure:	Causes burns.
Inhalation exposure:	Damage to mucous membranes of airways, burns to mucous membranes, cough, shortness of breath, malaise, unconsciousness, headache, cardiac arrest.
Eye exposure:	Tearing, irritation, pain in the eye, clouded vision, severe eye injury. Risk of loss of vision.

Repeated dose toxicity (subacute, subchronic, chronic)

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

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

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

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
Carcinogenicity:	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
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11.2.	Practical experiences:	
	Classification observations:	No information available
	Other observations:	No information available

11.3.	General notes:
	-

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SECTION 12. General notes:						
12.1. Toxicity						
Acute (short-term) 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	72 hours	No information available	-	No information available	-
Other organisms	-	-	No information available	-	No information available	-
Chronic (long-term) 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	72 hours	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})						

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

Bioconcentration factor (BCF)

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

Chronic ecotoxicity

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

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

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

Adsorption / desorption

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

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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
	No information available

12.6.	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 Low:
	15 01 10*: packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3.	Waste treatment – relevant information:
	No information available

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

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

13.1.6.	Relevant Community provisions:
	Sustainable Waste Management Act, Ordinance on Waste Management, Regulation on categories, types and classification of waste with waste catalog and list of hazardous waste

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SECTION 14. Transport information	
Transporting/shipment by road (ADR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by inland waterways (ADN)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmental hazards:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	III
Environmental hazards:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3

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Packing group:	III
Environmental hazards:	-
Special precautions for user:	-

Further information:	<p>ADR: Special Provision 144 – An aqueous solution containing 24% or less alcohol by volume is not subject to classification.</p> <p>IATA: Special Provision A58 - An aqueous solution containing 24% or less alcohol by volume is not subject to classification.</p>
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SECTION 15. Regulatory information	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorisations and/or restrictions of use
	Authorisations: -
	Restrictions: -
	Other EU regulations: EC Regulation No. 1906/2007 and Directive (EC) No. 1272/2008 of the European Parliament and Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council regarding registration, evaluation, authorization and restriction of chemicals (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council from 29 April 2004 about persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council from 19 November 2008 about waste and repeal of certain Directives
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)
	National regulation: Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Transport of Hazardous Substances Act
15.2.	Chemical safety assessment
	None

SECTION 16. Other information	
16.1.	Indication of changes: -

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16.2.	Abbreviations and acronyms:	PBT vPvB LD ₅₀ LC ₅₀ STOT-SE	Stable, bioaccumulative and toxic Strongly stable and strongly bioaccumulative.. Lethal dose, 50% Lethal concentration, 50% Specific target organ toxicity – single exposure
16.3.	Key literature references and source of data:	-	
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)		
	Classification	Classification procedure	
	-	-	
16.5.	Relevant H statements (number and full text)		
	H:	H225 H226	Highly flammable liquid and vapour. Flammable liquid and vapour.
16.6.	Training advice:	-	
16.7.	Further information:	** "X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.	

ANNEX:
EXPOSURE SCENARIO RESULTING TO CHEMICAL SAFETY ASSESSMENT
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