

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

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>Sternheimer-Malbin</u> 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.	-
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:	-

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

	Hazard pictograms:	-
	Signal word:	-
	Hazard statement:	-
	Precautionary statements:	-
	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)
-	-	-	Not identified as hazardous substance.	-

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:	-
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Cough, breathing difficulties, respiratory failure, dizziness, euphoria, narcosis, inebriation.
	Following skin contact:	Drying and cracking of skin, redness, burning sensation, burns with ulceration.
	Following eye contact:	Redness, burning sensation, tearing, eye pain, blurred vision, severe eye damage. Hazard of permanent loss of vision.

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

	Following ingestion:	Burns of the mouth and throat, pain in the digestive tract, nausea, vomiting, perforation of the esophagus and stomach.
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:	Water, CO ₂ , foam, dry powder
	Unsuitable extinguishing media:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	No information available.
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 protective equipment in accordance with Section 8. Do not get in eyes or on skin. Do not inhale vapor/aerosols. Remove the persons not directly involved in rescuing procedure from the scene of event.
	Accident prevention methods:	Keep away from heat, flames and sparks. Secure proper ventilation. Prevent electrostatic charge buildup. Use only grounded devices and equipment. Do not release in drains - explosion hazard.
	Emergency procedures:	In case of accident secure the location and evacuate the personnel not involved in recovery.
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:	

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

	Prevent the product from entering the environment; in case it enters environment, it is necessary to prevent the product from reachign waterways, drainage systems and soil. In the case of considerate 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 bags.
6.3.2.	Cleaning up:	Where possible, soak up the product using inert matter, such as sand, silica gel, saw dust). 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 and involved materials with water.
6.3.3.	Other information:	Recovery of contaminated area should only be conducted by qualified person that uses stipulated protective equipment. Prevent the waste water from entering waterways.
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:	Keep away from heat, flames and sparks. Secure proper ventilation.
	Measures to prevent aerosol and dust generation:	Adequate ventilation of the rooms where the product is kept and handled. Containers must be firmly closed.
	Measures to protect the environment:	Keep the containers firmly closed in vertical position when the product is not used. Prevent the product from entering waterways, sewerage and drainage systems by using barrage and semi-barrage made of sand, as well as covering the drainage by using plastic foil.
	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	

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

Technical measures and storage conditions:	In dry, cold and well-ventilated space. Containers must be firmly closed. Maintain adequate ventilation of the rooms where the product is kept and handled.
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:	Keep away from heat, flames, sparks and sunlight.
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:	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	
-	-	-	-	-
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	-	-	-	-

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

Inhalation	-	-	-	-
Dermal	-	-	-	-

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

8.2. Exposure controls

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).

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

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
	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:	No information available	No information available
	Odour threshold;	No information available	No information available
	pH:	No information available	No information available
	Melting point / freezing point;	No information available	No information available
	Initial boiling point and boiling range:	No information available	No information available
	Flash point:	No information available	No information available
	Evaporation rate:	No information available	No information available
	Flammability (solid, gas):	No information available	No information available
	Upper/lower flammability or explosive limits:	No information available	No information available
	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

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available

9.2.	Other information
	-

SECTION 10.: Stability and reactivity		
10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	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	No information available	-	No information available	-
-Dermal:	No information available	No information available	-	No information available	-
Inhalation:	No information available	No information available	-	No information available	-
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects	Target organ	Note		
Oral:	No information available	No information available	-		
Dermal:	No information available	No information available	-		
Inhalation:	No information available	No information available	-		

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

	Aspiration hazard:		May cause respiratory irritation.			
	Irritation and corrosion					
	Exposure time		Species	Evaluation	Method	Note
Skin corrosion/irritation:	-		-	-	-	No information available
Serious eye damage/irritation	-		-	-	-	No information available
	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	-

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

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

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

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

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)

Carcinogenicity:	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
--	--------------------------

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

11.2.	Practical experiences:
	Classification observations: No information available
	Other observations: No information available
11.3.	General notes:
	-

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	No information available	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	-

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

	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 Kow)						
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	

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

	No information available	No information available	No information available	No information available	-

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

12.5.	Results of PBT and vPvB assessment
	No information available
12.6.	Other adverse effects
	No information available

SECTION 13. Disposal considerations	
13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to 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:

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

	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

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:	-

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	Not subject to transport regulations
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:	-
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
	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)

Trade name:	URIGNOST SM REAGENT				
Product code:	UGSM-X**	Date of compilation:	05 July 2019	Version:	2

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