

Trading name:	TB FUCHSIN REAGENT				
Product code:	TBFR-OT-X**	Date of compilation:	27.09.2019.	Version:	1

SECTION 1. Identification of the substance/mixture and of the company/undertaking		
1.1	Product identifier	
	Trading name:	TB FUCHSIN REAGENT
	Chemical name:	-
	Catalogue number:	TBFR-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use with TB-Stain ECO kit.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device and there is no reason to use it for other purposes
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	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 substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Flam. Liq. 3	H226
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2	Label elements	
	Product identification:	TB FUCHSIN REAGENT
	Identification number:	-
	Authorization number:	-

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Hazard pictograms:	
	GHS02
Signal word:	Warning
Hazard statements:	H226 Flammable liquid and vapor
Precautionary statements	P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. 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 no.	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	< 20 %	ethanol	Flam. Liq. 2; H225

SECTION 4. First aid measures

4.1	Description of first aid measures
General notes:	If the symptoms remain, immediately call a physician.
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. Provide oxygen if difficult breathing occurs.
Following skin contact:	Remove contaminated clothes. Immediately wash with copious amounts of water, rinse for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
Following eye contact:	Wash with copious amounts of water with eyelids wide open, rinse for at least 20 minutes. In case of persisting symptoms, immediately contact ophthalmologist.
Following ingestion:	Rinse the oral cavity and drink 1-2 glasses of water. Immediately contact physician and show them the bottle 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 sensation, digestion tract mucosa irritation, stomach pains, nausea, and vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	No information available
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Incomplete combustion of the product.
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.	

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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:	Absorb using absorbing material. Dispose of the waste material in a tightly closed impermeable container. Store the product in a well-ventilated storage room until disposal. Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection. After disposing of the product, wash the room and materials that were in contact with the product.
6.3.3.	Other information:	Do not store with 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.	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 sparking.
	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.

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

SECTION 8. Exposure controls/personal protection				
8.1	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
ethanol	64-17-5	1000/-	1900/-	-
Substance name: -				
EC No: - CAS No -				
DNEL				
Industrial				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)
Critical physical parameters: solubility, flammability, corrosivity: -				
Consumer				
Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)
PNEC				
Environmental protection target		PNEC		
Fresh water		0.96 mg/l (ethanol)		
Freshwater sediments		3.6 mg/kg (ethanol)		
Marine water		0.79 mg/l (ethanol)		
Marine sediments		No information available		

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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 in well ventilated storage 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 the area for rinsing eyes and showering.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection:	Protective eyeglasses that stick to face, or a visor in case of lower concentration in air; protective mask that covers the entire face in case of higher concentration in air.
8.2.2.2. Skin protection	
Hand protection:	Protective gloves must be according to the EU Directive EU 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: 0.40 mm Time until perforation: > 480 min
Other skin protection:	During everyday work use cotton clothing and suitable footwear, such as rubber boots 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:	Full protective face mask or half mask equipped with organic fumes filter, type A (boiling point >65°) in case concentration exceeds 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.

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Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties			
9.1	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Color:	dark violet	No information available
	Odor:	ethanol	No information available
	Odor threshold:	No information available	No information available
	pH:	4.5 -5.0	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:	47 °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
	Vapor pressure:	No information available	No information available
	Vapor density:	No information available	No information available
	Relative density:	No information available	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	Soluble in water (20 °C)	No information available
	Partition coefficient: n-octanol/water (log Kow):	No information available	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	Viscosity:	No information available	No information available
	Explosive properties:	No information available	No information available
	Oxidising properties:	No information available	No information available
9.2	Other information		
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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 stable under standard ambient conditions of storing and using.

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10.3	Possibility of hazardous reactions:	Risk of explosion after contact with strong acids, alkali metals, alkali metal oxides, nitric acid, oxidizing substances.
10.4	Conditions to avoid:	High temperatures, ignition sources, open flame.
10.5	Incompatible materials:	Oxidants, acids, alkali metals.
10.6	Hazardous decomposition products:	Nonbiodegradable in case of using in the described way.

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 exposure:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg	
Dermal exposure:	-	-	-	-	-	
Inhalation exposure:	-	rat (ethanol)	LC ₅₀	4 h	20.000 mg/l	
	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		-	
	Aspiration hazard:		No information available			
	Irritation and corrosion					
	Exposure time		Species	Evaluation	Method	Note
Skin corrosion/irritation:	-		-	-	-	-
Serious eye damage/irritation	-		-	-	-	-
	Sensitization					
Dermal exposure:		No information available				
Respiratory sensitization:		No information available				
	Symptoms related to the physical, chemical and toxicological characteristics					
Oral exposure:		No information available				

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

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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
	<i>In vitro</i> mutagenicity:	No information available
	Genotoxicity:	No information available
	<i>In vivo</i> mutagenicity:	No information available
	Germ cell mutagenicity:	No information available
	Reproductive toxicity:	No information available
	Summary of evaluation of the CMR properties:	No information available

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

SECTION 12. Ecological information						
12.1	Toxicity					
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	-	-	-	-
Crustacea:	EC ₅₀	48 hours	-	-	-	-
Algae/aquatic plants	IC ₅₀	4 days	-	-	-	-
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

Partition coefficient: n-octanol/water (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

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

12.4 Mobility in soil

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

Adsorption / desorption

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

12.5 Results of PBT and vPvB assessment

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 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 empty remnants of the product into drains. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the remains to the collectors authorized by the ministry in charge.
13.1.6.	Relevant Community provisions:
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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

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

Further information:	ADR: Special provision 144 - Aqueous solution containing 24% or less alcohol volume, not subjected to classification. IATA: Special provision A58 - Aqueous solution containing 24% or less alcohol volume, not subjected to classification.
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SECTION 15. Regulatory information	
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorization and/or restrictions of use
	Authorizations: -
	Restrictions: -

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Other EU regulations:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council from 29 June 2000 on substances that damage the ozone layer; EC Regulation No. 689/2008 of the European Parliament and Council of 17 November 2008 on waste and repealing certain Directives EC Regulation No. 850/2004 of the European Parliament and Council from 29 June 2004 on persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
National legislation:	Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act
15.2	Chemical safety assessment
	No information

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 LD₅₀ Lethal dose, 50% LC₅₀ 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: H225 H226	Highly flammable liquid and vapor. Flammable liquid and vapor.
16.6.	Training advice:	-

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16.7.	Further information:	"X" in the product code marks different volumes (different packagings of the product) We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.
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ANNEX: Exposure scenario resulting to Chemical safety assessment
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