

Trade name:	TISSUE MARKING DYES, BLACK			
Product code:	3408-3-X**	Date of compilation:	13 May 2019	Version: 4

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trading name:	TISSUE MARKING DYES, BLACK
	Chemical name:	-
	Product code:	3408-3-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For marking and orientation of tissue samples.
	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 Irrit. 2	H315
	Eye Irrit. 2	H319
2.1.2.	Additional information	
	-	
*For the full text of H and EUH phrases see Section 16.		
2.2.	Label elements	
	Product identification:	TISSUE MARKING DYES, BLACK
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	 GHS07
Signal word:	Warning
Hazard statement:	H315 Causes skin irritation H319 Causes serious eye irritation.
Precautionary statement:	P280 Wear protective gloves/protective clothing/eye/protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P337+P313 If eye irritation persists: Get medical advice/attention.
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)
67-63-0/ 200-661-7/ 603-117-00-0	-	<4	isopropyl alcohol	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336
7664-41-7 231-635-3/ 007-001-00-5	-	<1	ammonia	Flam.Gas 2; H221 Skin Corr. 1B; H314 Acute Tox. 3; H331 Aquatic Acute 1; H400

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 larynx irritation or cough occur, provide the afflicted person with fresh air. Seek medical assistance if the symptoms of irritation remain.

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	Following skin contact:	Rinse with water. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse with water. Seek medical assistance if the symptoms of irritation remain.
	Following ingestion:	If larynx irritation occurs, rinse mouth with water. Seek medical assistance if the symptoms of irritation remain.
	Self-protection of the first aider	-
4.2.	Most important symptoms and effects, both acute and delayed	
	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 contacts 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.
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	

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	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).	
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.

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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 9).
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	
Isopropanol	67-63-0	400/500	999/1.250	-
Ammonia	7664-41-7	20/50	14/36	-
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:	Safety glasses tested and approved under appropriate standards 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.

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Technical measures to prevent exposure:	See Section 6
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SECTION 9. Physical and chemical properties			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	Liquid	No information available
	Colour:	Black	No information available
	Odour:	Faint ammonia	No information available
	Odour threshold;	No information available	No information available
	pH:	8.5 -10.0	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:	> 93.3 °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	1.02 - 1.14 (20°C)	No information available
	Bulk density:	No information available	No information available
	Solubility(ies):	No information available	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		
	-		

SECTION 10.: Stability and reactivity	
10.1.	Reactivity: Not reactive under normal conditions.

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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).

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	LD ₅₀	No information available	5,045 mg/kg (isopropanol)	
Dermal:	No information available	rabbit	LD ₅₀	No information available	12,800 mg/kg (isopropanol)	
Inhalation:	No information available	rat	LC ₅₀	8 h (isopropanol) 4 h (ammonia)	16.000 ppm (isopropanol) 2.000 ppm (ammonia)	
	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:		-			
	Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note	

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Skin corrosion/irritation:	No information available	rabbit	-	-	mild skin irritation
Serious irritation to eyes:	No information available	rabbit	24 h	-	eye irritation

Sensitization

Skin sensitization:	May cause an allergic skin reaction.
Respiratory sensitization:	Allergic persons may display irritation.

Symptoms related to physical, chemical, and toxicological properties

Oral exposure:	No known specific symptoms. May cause discomfort if swallowed.
Dermal exposure:	No known specific symptoms. May cause discomfort.
Inhalation exposure:	No known specific symptoms. Aerosols/vapor may cause respiratory system irritation.
Eye exposure:	No known specific symptoms. May cause mild eye irritation.

Repeated dose toxicity (subacute, subchronic, chronic)

[illegible]

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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
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:	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 toxic effects on reproductive organs were noted during testing on animals.
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:
	-

SECTION 12. Ecological information							
12.1.	Toxicity						
Acute (short-term) toxicity		Dose	Exposure time	Species	Method	Evaluation	Note
Fish		LC ₅₀	96 hours	Pimephales promelas (fathead minnow)	-	-	9.640 mg/l (isopropanol)
Crustacea:		EC ₅₀	24 hours	Daphnia magna (water flea)	-	-	5.120 mg/l (isopropanol) 25.4 mg/l (ammonia)
Algae/aquatic plants:		IC ₅₀	72 hours	Desmodesmus subspicatus (green algae)	-	-	>2.000 mg/l (isopropanol)
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						

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

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

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

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	-

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	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 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.				

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13.1.6.	Relevant Community provisions:
	-

SECTION 14. Transport information

	Transporting/shipment by road (ADR)
UN number:	Not regulated
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by rail (RID)
UN number:	Not regulated
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 regulated
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
	Transporting/shipment by sea (IMDG)
UN number:	Not regulated
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 regulated

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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:	EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 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 of 29 June 2000 on ozone-depleting substances; 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 of 29 April 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	
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SECTION 16. Other information

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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% TCOJ Specific target organ toxicity - single exposure STOT - RE Specific target organ toxicity - repeated 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:	221 225 314 315 319 331 336 400	Flammable gas. Highly flammable liquid and vapour. Causes severe skin burns and eye damage. Causes skin irritation. Causes serious eye irritation. Toxic if inhaled. May cause drowsiness or dizziness. Very toxic to aquatic life.
16.6.	Training advice:		-
16.7.	Further information:		"X" in the product code marks different volumes (different packaging 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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