


Trade name:	<b>TISSUE MARKING DYES, BLACK</b>		
Product code:	3408-3-X**	Date of compilation:	14 November 2022
		Version:	5

<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>		
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:	<a href="mailto:msds@biognost.hr">msds@biognost.hr</a>
	National contact:	-
1.4.	Emergency telephone numbers	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

<b>SECTION 2. Hazards identification</b>		
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 Irr. 2	H315
	Eye Irr. 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:	-

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>			
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version: 5

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):	-
<b>2.3. Other hazards</b>	
No known endocrine disrupting properties. This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.	

<b>SECTION 3. Composition/information on ingredients</b>				
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	propan-2-ol	Flam. Liq. 2; H225 Eye Irr. 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

<b>SECTION 4. First aid measures</b>	
<b>4.1. Description of first aid measures</b>	
General notes:	Move out of dangerous area. Show this safety data sheet to the doctor and first responders.

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

	Following inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Get medical advice.
	Following skin contact:	Wash off with soap and plenty of water. If irritation occurs and persists: Get medical advice.
	Following eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation occurs and persists: Get medical advice.
	Following ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water.
	Self-protection of the first aider	-
<b>4.2.</b>	<b>Most important symptoms and effects, both acute and delayed</b>	
	Following inhalation:	No information available.
	Following skin contact:	No information available.
	Following eye contact:	No information available.
	Following ingestion:	No information available.
<b>4.3.</b>	<b>Indication of any immediate medical attention and special treatment needed</b>	
	Treat symptomatically.	

<b>SECTION 5. Firefighting measures</b>		
<b>5.1.</b>	<b>Extinguishing media</b>	
	Suitable extinguishing media:	Use dry chemical, CO <sub>2</sub> , water spray (FOG) or foam.
	Unsuitable extinguishing media:	Avoid solid water stream as it may scatter and spread fire.
<b>5.2.</b>	<b>Special hazards arising from the substance or mixture</b>	
	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).
<b>5.3.</b>	<b>Advice for firefighters</b>	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
<b>5.4.</b>	<b>Additional information</b>	
	Heating may cause container cracking due to increase in pressure. Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

<b>SECTION 6. Accidental release measures</b>	
<b>6.1.</b>	<b>Personal precautions, protective equipment and emergency procedures</b>
<b>6.1.1.</b>	For non-emergency personnel

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

	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.	Bundling, 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	
	-	

<b>SECTION 7. Handling and storage</b>		
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.

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

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).
<b>7.3. Specific end use(s)</b>	
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 <sup>3</sup>	
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	36 mg/ m <sup>3</sup> (ammonia)	47.6 mg/ m <sup>3</sup> (ammonia)	14 mg/ m <sup>3</sup> (ammonia)	500 mg/m <sup>3</sup> (propan-2-ol) 47.6 mg/ m <sup>3</sup> (ammonia)
Dermal	-	6.8 mg/kg bw/day (ammonia)	-	888 mg/kg bw/day (propan-2-ol) 6.8 mg/kg bw/day (ammonia)

Critical physical parameters: solubility, flammability, corrosivity: -

**Consumer**

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
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Trade name:	<b>TISSUE MARKING DYES, BLACK</b>		
Product code:	3408-3-X**	Date of compilation:	14 November 2022
		Version:	5

Oral	-	6.8 mg/kg bw/day (ammonia)	-	26 mg/kg bw/day (propan-2-ol) 6.8 mg/kg bw/day (ammonia)
Inhalation	-	-	-	89 mg/m <sup>3</sup> (propan-2-ol)
Dermal	-	6.8 mg/kg bw/day (ammonia)	-	319 mg/kg (propan-2-ol) 6.8 mg/kg bw/day (ammonia)

**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 personal protective equipment. Do not eat, drink or smoke in the workspace.
Structural measures to prevent exposure:	No information available
Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.

**8.2.2. Personal protection equipment:**

8.2.2.1. Eye and face protection:	Safety glasses tested and approved under appropriate standards such as EN 166(EU).
8.2.2.2. Skin protection:	
Hand protection:	Handle with chemical resistant gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

	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.	<b>Environmental exposure controls</b>	
	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

<b>SECTION 9. Physical and chemical properties</b>			
9.1.	Information on basic physical and chemical properties		
		Value	Method
	Physical state:	liquid	No information available
	Colour:	black	No information available
	Odour/odour threshold:	faint ammonia	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	> 93.3 °C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	8.5 -10.0	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density	1.02 - 1.14 (20°C)	No information available

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>			
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version: 5

Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
9.2. Other information	-	

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

SECTION 11. Toxicological information					
11.1. Information on toxicological effects	Acute toxicity:				
Route of exposure:	Method	Species	Effective Dose LD <sub>50</sub> /LC <sub>50</sub> or ATE <sub>mixture</sub>	Exposure time	Results
Oral:	No information available	rat	LD <sub>50</sub>	No information available	5.840 mg/kg (2-propanol)
Dermal:	No information available	rabbit	LD <sub>50</sub>	No information available	12.800 mg/kg (2-propanol)
Inhalation:	No information available	rat	LC <sub>50</sub>	8 h (isopropanol) 4 h (ammonia)	37.5 mg/l (2-propanol) 9.850 mg/m <sup>3</sup> air (ammonia)
Specific target organ toxicity - single exposure (STOT-SE):					
	Specific effects		Target organ	Note	
Oral:	No information available		-	-	





Trade name:	<b>TISSUE MARKING DYES, BLACK</b>					
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5	

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

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

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

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Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

Carcinogenicity:	Product not classified as a carcinogen by the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), or the Occupational Safety and Health Administration (OSHA).
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
<b>11.2. Information on other hazards:</b>	
<b>11.2.1. Endocrine disrupting properties:</b>	
No known endocrine disrupting properties that affect human health.	
<b>11.2.2. Other information:</b>	
-	

<b>SECTION 12. Ecological information</b>						
<b>12.1. Toxicity</b>						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	Pimephales promelas (fathead minnow)	-	-	9.640 mg/l (2-propanol)
Crustacea:	EC <sub>50</sub>	48 hours	Daphnia magna (water flea)	-	-	13.299 mg/l (2-propanol) 25.4 mg/l (ammonia)
Algae/aquatic plants:	IC <sub>50</sub>	72 hours	Desmodesmus subspicatus (green algae)	-	-	> 1.000 mg/l (2-propanol)
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish	LC <sub>50</sub>	96 hours	-	-	-	-
Crustacea:	EC <sub>50</sub>	48 hours	-	-	-	-

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>			
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version: 5

Algae/aquatic plants:	IC <sub>50</sub>	72 hours	-	-	-	-
Other organisms	-	-	-	-	-	-

**12.2. Persistence and degradability**

Abiotic degradation

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

Biodegradation

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

**12.3. Bioaccumulative potential**

Octanol-water partition coefficient (log K<sub>ow</sub>)

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

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

Chronic toxicity on fish	LC <sub>50</sub>	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (Daphnia)	EC <sub>50</sub>	No information available	No information available	No information available	No information available	-

**12.4. Mobility in soil**

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

**Adsorption / desorption**

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

**12.5. Results of PBT and vPvB assessment**

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

**12.6. Endocrine disrupting properties**

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

**12.7. Other adverse effects**

No information available

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

**SECTION 13. Disposal considerations**

13.1.	Waste treatment methods
13.1.1.	Product/Packaging disposal: Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
13.1.2.	Waste codes/waste designations according to Law: Disposal must be made according to official regulations.
13.1.3.	Waste treatment – relevant information: No information available
13.1.4.	Sewage disposal – relevant information: Waste must not be disposed of into the sewage system.
13.1.5.	Other disposal recommendations: Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.
13.1.6.	Relevant Community provisions: -

**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:	-

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

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
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-
Special precautions for user:	-
Further information:	-

<b>SECTION 15. Regulatory information</b>	
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
	EU regulations
	Authorisation and/or restrictions on use
	Authorisations: -
	Restrictions: -

Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

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

<b>SECTION 16. Other information</b>		
16.1.	Indication of changes:	-
16.2.	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	Manufacturer's MSDS file.



Trade name:	<b>TISSUE MARKING DYES, BLACK</b>				
Product code:	3408-3-X**	Date of compilation:	14 November 2022	Version:	5

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 Flammable gas. 225 Highly flammable liquid and vapour. 314 Causes severe skin burns and eye damage. 315 Causes skin irritation. 319 Causes serious eye irritation. 331 Toxic if inhaled. 336 May cause drowsiness or dizziness. 400 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.

<b>ANNEX: Exposure scenario resulting to Chemical safety assessment</b>
-