

SAFETY DATA SHEET
According to Regulation (EC) No. 1907/2006

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Trade name:	GELATINE, SOLUTION				
Product code:	GEL-OT-X**	Date of compilation:	13 March 2017	Version:	3

SECTION 1: Identification of the substance/mixture and of the company/undertaking	
1.1. Product identifier	
Trade name:	GELATINE, SOLUTION
Chemical name:	-
Catalogue number:	GEL-OT-X**
1.2. Relevant identified uses of the substance or mixture and uses advised against	
Uses:	For use in histology.
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, registered at the Agency for Medicinal Products and Medical Devices 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:	00-385-1-2404039
e-mail of competent person:	vladimir.ramljak@biognost.hr
National contact:	Vladimir Ramljak, professor of biology
1.4. Emergency telephone numbers	
National Protection and Rescue Directorate:	112
Medical information:	01-23-48-342
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*:
-	-
2.1.2. Additional information	
-	
* For full text of Hazard- and EU Hazard-statements: see SECTION 16	
2.2. Label elements	
Product identification:	GELATINE, SOLUTION
Identification number:	-
Authorisation number:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement:	-

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	Precautionary statement:	-
	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)
-	-	-	Contains no hazardous substances	-

SECTION 4. First aid measures

4.1.	Description of first aid measures	
	General notes:	-
	Following inhalation:	In case of inhaling, take the afflicted person out for fresh air. If the afflicted person stops breathing, apply artificial respiration. Consult a physician.
	Following skin contact:	Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.
	Following eye contact:	Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.
	Following ingestion:	Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorized by a doctor.
	Self-protection of the first aider	Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause mucous membrane irritation and respiratory depression.
	Following skin contact:	May cause irritation.
	Following eye contact:	Irritation and swelling may occur after direct contact with eyes.
	Following ingestion:	Swallowing may cause stomach pains, nausea, vomiting.
4.3.	Indication of any immediate medical attention and special treatment needed	
	No information available	

SECTION 5. Firefighting measures

5.1.	Extinguishing media
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	Suitable extinguishing media:	Water spray, alcohol-resistant foam, dry chemical powder or carbon dioxide.
	Unsuitable extinguishing media:	No information available
5.2.	Special hazards arising from the substance or mixture	
	Hazardous byproducts of fire:	No information available
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4.	Additional information	
	No information available	

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. Use personal protective equipment. Prevent dust formation. Do not inhale vapor/mist/gases. Secure proper ventilation. Avoid inhaling dust.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Wear 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.	For bunding, covering of drains; capping procedures:	Sweep and collect in one pile.
6.3.2.	For cleaning:	Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
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.	Protective measures	
	Measures to prevent fire:	No information available.

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	Measures to prevent aerosol and dust generation:	Do not get in eyes or on skin. Avoid forming dust and aerosols. Enable appropriate exhaust ventilation in places where dust accumulates.
	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, and away from sources of heat, sunlight, and other incompatible substances.
	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.
	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	
Contains no hazardous substances	-	-	-	-
Substance:	-			
EC No:	-	CAS No:	-	
DNEL				
Industrial				

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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
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:	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 that stick to face (preventing splashing) or visor.
8.2.2.2.	Skin protection	

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	Hand protection:	Protective gloves for long-time work (over 8 h) made of following materials: - polychloroprene, 0.5 mm, - nitrile rubber, 0.35 mm, - butyl rubber, 0.5 mm, - polyvinyl chloride, 0.5 mm.
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves, and shoes that cover the entire foot.
8.2.2.3.	Respiratory protection:	Use a protective mask or a half mask with A-P3 combined filter (brown-white).
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:	Gelatinous liquid	No information available
	Colour:	Colorless	No information available
	Odour:	Mild	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

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Relative density	No information available	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
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SECTION 10.: Stability and reactivity

10.1.	Reactivity:	No information available
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available
10.4.	Conditions to avoid:	None in particular. However the usual precautions used for chemical products should be respected.
10.5.	Incompatible materials:	No information available
10.6.	Hazardous decomposition products:	No information available

SECTION 11. Toxicological information

11.1.	Information on toxicological effects
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	Acute toxicity:
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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	-	No information available
Dermal:	No information available	No information available	No information available	-	No information available
Inhalation:	No information available	No information available	No information available	-	No information available

	Specific target organ toxicity - single exposure (STOT-SE):
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	Specific effects	Target organ	Note
Oral:	No information available	No information available	-

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Dermal:	No information available	No information available	-
Inhalation:	No information available	No information available	-

Aspiration hazard:	No information available
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Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation	No information available				
Serious eye damage/irritation	No information available				

Sensitization

Skin sensitization:	No information available
Respiratory sensitization:	No information available

Symptoms related to the physical, chemical and toxicological characteristics
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Oral exposure:	No information available
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	-				
Subacute dermal	No information available	-				
Subacute inhalation	No information available	-				
Subchronic oral	No information available	-				
Subchronic dermal	No information available	-				

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

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

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SECTION 12. Ecological information

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	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants:	IC ₅₀	8 days	No information available	No information available	No information available	-
Other organisms:	LC ₅₀	72 hours	No information available	No information available	No information available	-
Chronic (long-term) toxicity	Doza	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
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
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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				

Chronic ecotoxicity

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

12.4. Mobility in soil

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

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

12.5.	Results of PBT and vPvB assessment
	No information available

12.6.	Other adverse effects
	No information available

SECTION 13. Disposal considerations

13.1.	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2.	Waste codes/waste designations according to Low:
	No information available

13.1.3.	Waste treatment – relevant information:
	No information available

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

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

13.1.6.	Relevant Community provisions:
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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.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmental hazards:	-

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Special precautions for user:	-
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Further information:	The product is not subject 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	
	Authorisation and/or restrictions on use	
	Authorisations:	-
	Restrictions:	-
	Other EU regulations:	<p>EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council;</p> <p>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);</p> <p>EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances;</p> <p>EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals;</p> <p>EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants;</p> <p>Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives</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	
	None	

SECTION 16. Other information

16.1.	Indication of changes:		-
16.2.	Abbreviations and acronyms:		<p>PBT Stable, bioaccumulative and toxic</p> <p>vPvB Strongly stable and strongly bioaccumulative</p> <p>LD₅₀ Lethal dose, 50%</p> <p>LC₅₀ Lethal concentration, 50%</p> <p>STOT - SE Specific target organ toxicity - single exposure</p>

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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:	<p>** "X" in the product code marks different volumes (different packaging of the product)</p> <p>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.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment
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