

Trade name:	EA 65 REAGENT, PAP 3C				
Product code:	EA65C-OT-X**	Date of compilation:	05 June 2019	Version:	1

SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1.	Product identifier	
	Trade name:	EA 65 REAGENT, PAP 3C
	Chemical name:	-
	Catalogue number:	EA65C-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	Cytoplasmic staining reagent acc. to Papanicolaou –red hue.
	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:	+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*:
	Flam. Liq. 2	H225
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16.		
2.2.	Label elements	
	Product identification:	EA 65 REAGENT, PAP 3C
	Identification number:	-
	Authorisation number:	-

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Hazard pictograms:	
	GHS02
Signal word:	Danger
Warning statement:	H225 Highly flammable liquid and vapor.
Precautionary statement:	P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
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)
64-17-5/ 200-578-6/ 603-002-00-5	-	≥ 70	ethanol	Flam. Liq. 2; H225

SECTION 4. First aid measures		
4.1.	Description of first aid measures	
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.	
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.	
Following skin contact:	Remove all contaminated clothes/footwear. Thoroughly wash with water for at least 15 minutes.	
Following eye contact:	Rinse the eyes using mild jet of clean water for at least 20 minutes with the eyelids held wide open.	
Following swallowing:	Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.	

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	Self-protection of the first aider	-
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 swallowing:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, 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	
	Suitable extinguishing media:	Small fire - water spray, dry powder, alcohol-resistant foam, CO2 Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	Water with full jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous byproducts of fire:	Incomplete combustion of the product.
5.3.	Advice for firefighters	
	Stay in danger area only with self-contained open-circuit compressed air breathing apparatus and a set for protecting the body from heat dissipation (fireproof clothing).	
5.4.	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. 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. Keep away from ignition sources.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	

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	Self-contained open-circuit compressed air breathing apparatus, a set for protecting the body from heat dissipation (fireproof clothing).	
6.2.	Environmental precautions:	
	Use sand protective barrier to prevent further spillage of chemicals. Prevent environmental pollution by not allowing the chemicals to enter the sewage system, surface water or groundwater.	
6.3.	Methods and materials for containment and cleaning up	
6.3.1.	Bunding, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials
6.3.2.	Cleaning up:	Sawdust, sand, mineral adsorbents
6.3.3.	Other information:	Secure proper ventilation. Contact the responsible person; in case of larger spills and possible environmental pollution contact National Protection and Rescue (112). Do not use incompatible materials (see Section 10).
6.4.	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

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 sparks. Do not smoke.
	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:	Protect against electrostatic charges.
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. Protect from heat and direct sunlight.
	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/-	No information available
Substance:		-		
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	-	-	-	950 mg/m ³ (ethanol)
Dermal	-	-	-	343 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		
Food chain		no information available		

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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:	Do not eat, drink or smoke in the workspace. Use personal protective equipment.
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:	See Section 7.2

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
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8.2.2.2. Skin protection

Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
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Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) 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.
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8.2.2.3. Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
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8.2.2.4. Thermal hazards:	No information available
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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

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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:	pink with green glint	no information available
	Odour:	ethanol like	no information available
	Odour threshold;	no information available	no information available
	pH:	5.2-5.7	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:	15°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	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:	The product is stable under normal working and storage conditions.
10.2.	Chemical stability:	The product is chemically 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:	Avoid heat, sparks, open flames and other ignition sources.
10.5.	Incompatible materials:	Oxidants, acids, alkali metals.
10.6.	Hazardous decomposition products:	Non-degradable if used in the described manner.

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	-	7.060 mg/kg (ethanol)	
Dermal:	No information available	-	-	-	-	
Inhalation:	No information available	rat	LC ₅₀	4 h (ethanol)	20.000 mg/l (ethanol)	
	Specific target organ toxicity - single exposure (STOT-SE):					
	Specific effects			Target organ	Note	
Oral:	No information available			No information available	-	
Dermal:	No information available			No information available	-	
Inhalation:	No information available			No information available	-	
	Aspiration hazard:		No information available			
	Irritation and corrosion					
	Exposure time	Species	Evaluation		Method	Note
Skin corrosion/irritation	No information available	No information available	No information available		No information available	-
Serious eye damage/irritation	No information available	No information available	No information available		No information available	-
	Sensitization					
Skin sensitization:	No information available					

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Respiratory sensitization:	No information available
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Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Swallowing may cause irritation of mucosa, tingling sensation in the mouth, burning sensation; higher levels of concentration may cause nausea, abdominal pain and vomiting. In case of vomiting, aspiration causes coughing, difficult breathing. Higher levels of concentration may cause suffocation.
Dermal exposure:	Slight irritation. After short exposure, resorption effects are not likely. Long-term exposure may cause drying, cracking and tingling sensation of skin.
Inhalation exposure:	Inhalation of large amounts of vapors in inadequately ventilated perimeter may cause coughing, sneezing, headache and nausea.
Eye exposure:	Direct eye contact may cause slight to moderate irritation, lacrimation and burning sensation.

Repeated dose toxicity (subacute, subchronic, chronic)

	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
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	-

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Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Specific target organ toxicity - repeated exposure (STOT-RE):						
		Specific effects		Target organ		Note
Subacute oral		No information available		No information available		-
Subacute dermal		No information available		No information available		-
Subacute inhalation		No information available		No information available		-
Subchronic oral		No information available		No information available		-
Subchronic dermal		No information available		No information available		-
Subchronic inhalation		No information available		No information available		-
Chronic oral		No information available		No information available		-
Chronic dermal		No information available		No information available		-
Chronic inhalation		No information available		No information available		-
CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)						
Carcinogenicity:			No information available			
Mutagenicity <i>in-vitro</i> :			No information available			
Genotoxicity:			No information available			
Mutagenicity <i>in-vivo</i> :			No information available			
Germ cell mutagenicity :			No information available			
Reproductive toxicity:			No information available			
Summary of evaluation of the CMR properties; :			No information available			
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

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Fish	LC ₅₀	96 hours	-	No information available	-	-
Crustacea:	EC ₅₀	48 hours	-	No information available	-	-
Algae/aquatic plants:	IC ₅₀	72 hours	-	No information available	-	-
Other organisms	-	-	-	-	-	-

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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12.3.	Bioaccumulative potential					
	Octanol-water partition coefficient (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					
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	-	
	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	-	

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Water-Air	No information available	No information available	No information available	No information available	-
Soil-Air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

No information available

12.6. Other adverse effects

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2. Waste codes/waste designations according to Low:

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 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:

Disposal must be made according to official regulations.

SECTION 14. Transport information

Transporting/shipment by road (ADR)

UN number 1170

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UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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:	II
Environmental hazards:	No information available
Special precautions for user:	-

Transporting/shipment by inland waterways (ADN)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
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:	II
Environmental hazards:	No information available
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:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmental hazards:	No information available
Special precautions for user:	-

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Further information:	-
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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:	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	
	None	

SECTION 16. Other information			
16.1.	Indication of changes:	-	
16.2.	Abbreviations and acronyms:	PBT	Stable, bioaccumulative and toxic
		vPvB	Strongly stable and strongly bioaccumulative.
		LD50	Lethal dose, 50%
		LC50	Lethal concentration, 50%
		STOT-SE	Specific target organ toxicity – single exposure

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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:	H225	Highly flammable liquid and vapor.
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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