MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product name and reference

Biosynex® Bladder Tumor Antigen
Réf: 1110004

1.2. Product use

The BIOSYNEX® Bladder Tumor Antigen cassette test is a simple one step immuno-chromatographic assay for the rapid, detection of Bladder Tumor Marker in urine. Each test is used to obtain a qualitative result. The BIOSYNEX® Bladder Tumor Antigen Test Device can be used as an aid to initiate or attend therapeutic treatments by physicians. Each device is designed for professional and in-vitro diagnostic.

1.3. Company identification

Biosynex
22, boulevard Sébastien Brant
67400 ILLKIRCH - GRAFFENSTADEN

Tel.: 0033 388 78 78 87
Fax: 0033 388 78 76 78
Mail: client.pro@biosynex.com
Internet: www.biosynex.com

1.4. Emergency call

Numéro d'appel d'urgence Européen: 112
France: SAMU: 15
Number ORFILA: 01 45 42 59 59 (provides access to the list of poison centers and their phone number)
Other country: See your local poison information center.

1. HAZARD IDENTIFICATION

2.1 Classification of the mixture

➢ **Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]**

The product contains Sodium azide at a concentration ≤ 0.1 %. So this product is not a hazardous mixture as defined by the Regulation 1272/2008, and it is not classified as dangerous .
Information about the sodium azide being present in the product is related on parts 2.3 and 3.
The product also contains some substances from animal origin. It is therefore recommended to handle it according to the convenient procedures relative to infectious material.

2.2 Label elements

Regarding Regulation 1272/2008, no particular statement is required since the product is not considered as hazardous.

➢ **Labelling according Regulation (EC) No 1272/2008 [CLP]**

No need

➢ **According to European Directive 67/548/EEC as amended.**

No need

2.3 Other hazards (relative to sodium azide)

Even in small amount, Sodium azide may react with lead and cooper plumbing to form highly explosive metal azides. Sodium azide is also rapidly absorbed through skin.

2. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Product information

Cf. description of hazardous and non-hazardous components

3.2. Hazardous components:

Description	CAS Number	Einecs Number	Origin	Concentration in the final product	Hazard classification and risk phrase*
Sodium azide	26628-22-8	247-852-1	Chemical	0.05%	Regulation (EC) No 1272/2008 [CLP]: Acute toxicity 2, Acute aquatic toxicity 1, Chronic aquatic toxicity 1 H300, H410
Tris (hydroxymethyl)aminomethane	83147-39-1	201-064-4	chemical	20mM	Skin and eye Irritant, Category 2, Specific target organ toxicity 3
Sodium borate	1330-43-4	215-540-4	chemical	20mM	Reproductive toxic, Category 1 B
Triton-X100	9002-93-1	NA	chemical	<0.1%	Acute toxicity, Oral (Category4), H302 Eye irritation (Category 2), H319 Chronic aquatic toxicity (Category 2), H411

*For the full text of H-statements and R-Phrases mentioned in this section, see Section 16

3.3. Non-hazardous compounds:

Device for : In vitro diagnostics medical device. Test strip impregnated with dried chemical/biochemical reagents. Solid base plate, sample absorption paper, colloidal gold pad, and nitrocellulose membrane.
The test cassette contains a nitrocellulose membrane strip with 1) an immobilized antibody in the test reaction line (T). 2) an immobilized antibody reference line (R) marker, 3) Another immobilized e antibody as the control reaction line (C), on the nitrocellulose membrane
Materials: nitrocellulose membrane, PBS/Triton X for membrane blocking and washing, TRIS (2.4 %)-buffer sprayed on the membrane, adhesive plastic backing, polyester, 2 absorbent filters of glass fiber or cotton, plastic cassette, sodium azide for stabilization

3.4. Confidential compounds
N/A

3. FIRST AID MEASURES

General information	Consult a physician. Show this safety data sheet to the doctor in attendance.
After inhalation	Expose to fresh air. If breathing difficult, give oxygen. Consult a physician.
After skin contact:	Rinse with water and soap for at least 15 minutes. Consult a physician if irritation extended.
After eye contact:	Flush with water for at least 15 minutes. If possible remove contact lenses. Consult doctor in case of prolonged irritation.
After swallowing:	Rinse mouth. Contact the Poison Control Center.

5. FIRE FIGHTING MEASURES

Suitable extinguishing measures:	No special measures. Adapt the measure to the environment.
Extinguishing measures to avoid:	No special measures
Special risk:	Fire may produce dangerous products of decomposition like Carbon oxides, Nitrite oxides, Sodium oxides, and Nitrogen oxides in very negligible quantity. No more special risk
Special protective equipment for the firefighting :	Wear self-contained breathing if necessary.

6. ACCIDENTAL RELEASE MEASURES

If any doubt, contact the person in charge of hygiene and safety.

6.1. Measure for individual protection:
Use lab coat and gloves.

6.2. Measure for environmental protection:
Avoid release to the environment. The used testing materials should be discarded in accordance with local, state and/or federal regulations.

6.3. Measures for cleaning and waste collection:
Collect the test in containers according to official regulation.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling:
Use individual protective equipment (lab coat and gloves) for biological compound handling

7.2. Conditions for safe storage, including any incompatibilities:

Information about storage in one common storage facility:	The equipment must be stored between 2 and 30 ° C
Further information about storage condition:	Do not freeze

7.3. Particular use:
Professional in-vitro use only, See instruction for use.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION GEAR

8.1. Exposition cut off:
The product does not contain any element that exceeds the regulatory exposure limit value.
Sodium azide: VLE= 0,3 mg/m^3
Sodium azide: VME= 0,1 mg/m^3

8.2. Individual exposure control:

Respiratory exposure	NA
Hand exposure	Gloves recommended
Eyes exposure	NA
Skin exposure	Port of the coat

8.3. Environmental exposure control:
Collect test in containers according to the official local regulation.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information:

	Device
Aspect	Solid
Color	white

Odor	N/A

9.2. Important information relatives to health, safety and environment:

pH	neutral
Boiling point/range	N/A
Melting point/range	N/A
Inflammability	None
Explosion limit	None
Ignition temperature	N/A
Self-ignition	N/A
Flash point	N/A
Danger of explosion	N/A
Explosion limit	N/A
Relative vapor density 20 °C	N/A
Density at 20 °C	N/A
Solubility in water at 20 °C	N/A

9.3. Other information

NA

10. STABILITY AND REACTIVITY

10.1. Chemical stability:

No decomposition if used according to specifications

10.2. Reactivity:

Avoid contact with acidic solutions and metal compounds

10.3. Conditions to avoid:

Do not freeze

10.4. Incompatible materials:

Halogenated hydrocarbon, Metals, strong Acid, Strong oxidizers, Acid chlorides

10.5. Hazardous decomposition products:

Vapors of chlorine, hydrochloric acid, hydrazoic acid can be formed in negligible quantities.

11. TOXICOLOGICAL INFORMATION

Immediate effects on health: No data available

Differed and chronic effects on health:

Sensitization no data available

Carcinogenicity	no data available
Mutagenicity	no data available
Toxicity for reproduction	no data available
Specific effects from particular compounds:	No more known effects than described in phrase risk.

12. ECOLOGICAL INFORMATION

12.1. Toxicity
For Sodium azid: Toxicity to daphnia and other aquatic invertebrates:
EC50 - Daphnia pulex (Water flea) - 4,2 mg/l - 48 h
No more data available

12.2. Persistence and degradation
No data available

12.3. Bio accumulative potential
No data available

12.4. Mobility in soil
No data available

12.5. Results of PBT and vPvB assessment
No data available

12.6. Other adverse effects
Very toxic to aquatic life with lasting effects

13. DISPOSAL CONSIDERATION

Products - recommendation:
Disposal must be made according to official regulation of medical samples elimination.

Unclean packaging - recommendation:
Must be decomposed together with household garbage.

14. TRANSPORT INFORMATION

14.1 UN number
ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name
ADR/RID: Not dangerous goods

IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)
ADR/RID:- IMDG: - IATA: -

14.4 Packaging group
ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards
ADR/RID: no IMDG Marine Pollutant: no IATA: no

14.6 Special precautions for user
No data available

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15. REGULATION

This MSDS complies with the requirements of Regulation (EC) No. 1907/2006

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
No data available

15.2 Chemical Safety Assessment
No data available. For this product, a chemical safety assessment was not carried out.

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16. OTHER INFORMATION

Text of H-codes and R-phrases mentioned in section 3

- ✓ Sodium azide

EC n°1272/2008 Regulation	
Hazards	Description
H300	Fatal if swallowed
H302	Harmful if swallowed
H319	Causes skin and serious eye irritation
H410	Very toxic to aquatic life with long lasting effects

The product is intended for in vitro diagnostic and destined to be used by health professionals. The BIOSYNEX® Bladder Tumor Antigen does not contain any hazardous substances beyond the limits (<0.1%). Sodium azide is present in really small quantity, the toxic risk is then considerably reduced and acceptable.
The information in this document is based on the state of our current knowledge of the product. This document is composed in accordance with the Rules and Regulations REACH 1907/2006/EC and Article 31 from Directive 2001/58/EC.

History (changes)

Revision	Date	Part	Reason/Changes
01	09/09/2016		Not applicable, new product
02	10/04/2019		New template