MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product name and reference

Biosynex® Strep A
1030005

1.2. Product use

Biosynex® Strep A is a rapid test for the qualitative detection of Streptococcus A antigens in throat swabs. This kit is used as an aid in the diagnosis of Strep A infections. This test is for professional use only.

1.3. Company identification

BioSynex
12 rue Ettore Bugatti CS28006
67038 STRASBOURG

Tel.: 0033 388 77 57 00
Fax: 0033 359 81 21 74
Mail: info@biosynex.com
Internet: www.biosynex.com

1.4. Emergency call

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

2. HAZARD IDENTIFICATION

2.1 Classification of the mixture

The product contains sodium azide at a concentration ≤ 0.1 %. So according to the classification rules related in the Regulation 1272/2008, this product is non-hazardous.
The reagent 1 contains sodium nitrite at a concentration 13.8 %. So according to the classification rules related in the Regulation 1272/2008, this product is hazardous.
Information about the sodium nitrite and 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, a particular statement is required since the product is considered as hazardous.

O Oxidizer

T Toxic

N Toxic to aquatic life

2.3 Other hazards (related to sodium azide and sodium nitrite)

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. Sodium nitrite may be toxic if it is swallowed.

3. 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 nitrite	7632-00-0	231-555-9	Chemical	13.8%	Oxidizing solids 3, Acute toxicity 3, Acute aquatic toxicity 1,
Sodium azide	26628-22-8	247-852-1	Chemical	≤ 0,1 %	Acute toxicity 2, Acute aquatic toxicity 1, Chronic aquatic toxicity 1 H300, H410

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

3.3. Non-hazardous compounds:

Strip: PE carrier, cellulose filter , glass fiber , nitrocellulose , antibodies, colour particles, proteins, surfactants, Buffer components, salts, carbohydrates, polymers and preservatives,

Diluent: Extraction reagent 1: Sodium nitrite
Extraction reagent 2: Citric acid

Packaging: Aluminium foil pouches, dessicant card

3.4. Confidential compounds

N/A

4. 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:
Do not throw the diluent into the sink.

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 dipstick and buffer in containers according to the official local regulation.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information:

	Device	Reagent 1	Reagent 2
Aspect	Solid	liquid	liquid
Color	white	red	colorless
Odor	N/A	N/A	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:	Possibility of irritation in contact buffer extraction with skin and eyes: Rinse thoroughly. Possibility of irritation if swallowed buffer extraction: Contact a poison control center.
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 nitrite:

Fish toxicity: LC50 – 0.94 - 1.92mg/l - 96h
Toxicity to daphnia and other aquatic invertebrates: EC50 – 12.5 mg/l - 48h

For Sodium azid: Toxicity to daphnia and other aquatic invertebrates:
EC50 - Daphnia pulex (Water flea) - 4,2 mg/l - 48 h

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

Due to its composition, the product is not concerned by the transport regulation for dangerous products.

Maritime Transport IMDG:	No constraints
Transport by road ADR:	No constraints
Transport by train OACI/IATA:	No constraints
Air transport RID:	No constraints

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.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
Product labeling complies with the 98/79//EC directive. No specific warning labeling is required.
This MSDS complies with the requirements of Regulation (EC) No. 1907/2006

15.2 Chemical Safety Assessment
Classification:
Reagent 1 :
13.8 % Sodium Nitrite


O Oxidizer


T Toxic


N Toxic to aquatic life

16. OTHER INFORMATION

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

✓ Sodium nitrite

EC n°1272/2008 Regulation	
Hazards	Description
H400	Very toxic to aquatic life
H272	May intensify fire; oxidizer
H301	Toxic if swallowed
P phrases	Description
P220	Keep/Store away from clothing/…/combustible materials
P273	Avoid release to the environment

✓ Sodium azide

EC n°1272/2008 Regulation	
Hazards	Description
H300	Fatal if swallowed
H410	Very toxic to aquatic life with long lasting effects
P phrases	Description
P264	Wash thoroughly after handling
P273	Avoid release to the environment
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

P501	Dispose of contents/container to an approval waste disposal plant
European Union Specific Hazard Statements	
EUH032	Contact with acids liberates very toxic gas

The product is intended for in vitro diagnostic and destined to be used by health professionals. Biosynex® Strep A (extraction buffer 1) does contain Sodium nitrite beyond the limits.
Both hazardous substances are 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.