MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product name and reference

BIOSYNEX Adenovirus/Rotavirus BSS Ref. SW40001

1.2. Product use

BIOSYNEX Adenovirus/Rotavirus BSS is an immunochromatographique rapid test for the detection of the adenovirus and the rotavirus in human feces. This kit is for professional use by biologists.

1.3.Company identification

Biosynex Swiss SA
Rue de Romont 29-31
CH-1700 Fribourg – Switzerland

Tel.: 026 552 51 52
Fax: 026 552 51 54
Mail: client.pro@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

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

The buffer contains a mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1) at a concentration < 0.1 %.

So, this product is not hazardous as defined by the Regulation 1272/2008. The whole test kit is not classified as dangerous or hazardous according to the above regulation

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 (EC) No 1272/2008 [CLP], no particular statement is required since the product is not considered as hazardous.

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

No need

2.3 Other hazards

None

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substances

No single substance, this test kit is classified as a mixture. Please refer to point 3.2.

3.2. Mixture:

Strip: Sample and conjugate pad: Glass fiber
Nitrocellulose
Anti-Adenovirus Antibodies coupled with latex
Anti-Rotavirus Antibodies coupled with latex
Goat Antibodies anti-mouse IgG
Anti-Rotavirus and anti-Adenovirus antibodies

Hazardous components:

Description	CAS Number	Einecs Number	Origin	Concentration in the final product	Hazard classification and risk phrase*
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9	N/A	Chemical	0,001%	Regulation (EC) No 1272/2008 [CLP]: Acute Tox. 3: H301-H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

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

4. FIRST AID MEASURES

Due to the low concentration of chemicals and the chromatographic nature of the assay personal damages are extremely unlikely if the test is done according to the instructions. So far no injuries have been reported that could be linked to the use of the rapid test. For safety reasons general First Aid measures for chemical substances will be listed nevertheless.

General information: Consult a physician. Show this safety data sheet to the doctor in attendance.

After inhalation: Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.

After skin contact: Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.

After eye contact: Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.

After swallowing: If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

5. FIRE FIGHTING MEASURES

Suitable extinguishing measures: The common fire extinguishes media can be used.

Extinguishing measures to avoid: No special measures.

Special risk: Not yet find.

Special protective equipment for the firefighting:
Special protection in case of fire-fighting is generally recommended.

6. ACCIDENTAL RELEASE MEASURES

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

6.1. Measure for individual protection:
Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

6.2. Measure for environmental protection:
Avoid release to the environment.

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:
General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must remove before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities:
Storage Conditions: see Package Insert (2 - 30°C).
Store in a cool dry place.

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

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION GEAR

8.1. Control parameters:

➢ **Components with workplace control parameters:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2. Exposure control:

Appropriate engineering controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

➢ **Personal protective equipment:**

Recommended because of the potentially infectious character of the sample material;

Respiratory exposure:	Use with adequate normal ventilation.
Hand exposure:	Disposable gloves (latex/natural rubber).
Eyes exposure:	Safety glasses.
Skin exposure:	Laboratory coat or similar garment should be worn.

8.3. Environmental exposure control:

No special environmental controls are required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information:

Kit with single-pouched test cassette (foil pouch). No smell in original unopened packaging.

Appearance:

Test (after having been removed from the pouch): test cassette with sample wheel and result window.

Odor:

No specific odor known

	test	Diluent
Aspect	Solid	liquid
Color	white	colorless
Odor	N/A	N/A

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

pH	7.0
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	1.850 g/cm3
Solubility in water at 20 °C	65 g/l at 20 °C

9.3. Other information
NA

10. STABILITY AND REACTIVITY

10.1. Chemical stability:
No decomposition if used according to specifications.

10.2. Reactivity:
Long term exposure to temperatures above 30°C disable the product.

10.3. Conditions to avoid:
Humidity, Heating up

10.4. Incompatible materials:
No special hazards known

10.5. Hazardous decomposition products:
No special hazards known

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. This kit contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

Toxicity Data for Hazardous Ingredients: There are currently no toxicity data available for the components of this kit.

12. ECOLOGICAL INFORMATION

12.1. Toxicity
No adverse effects on the environment are expected from the components of this kit.

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
No data available

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. Contaminated packaging must be disposed according to official local regulation too.

14. TRANSPORT INFORMATION

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

Transport conditions per Package Insert Instructions (2 -30°C).
Do not transport together with flammable goods.
Do not transport above +30°C.

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

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.

16. OTHER INFORMATION

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

EC n°1272/2008 Regulation	
Hazards	Description
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
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. BIOSYNEX Adenovirus/Rotavirus BSS does not contain any hazardous substances beyond the limits set by the INRS (<0.1%). 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.