

MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product name and reference

BIOSYNEX COVID-19 Ag BSS	Ref. SW40006
BIOSYNEX COVID-19 Ag BSX	Ref. SW40006_BSX
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag	Ref. 859256, 859257, 859258, 859261, 859262, 859263, 859385
BIOSYNEX COVID-19 Ag BSS self-test	Ref. 859269, 859270, 859284

1.2. Product use

In vitro diagnostic medical device: rapid in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or nasal swab specimens.

Ref. SW40006 and SW40006_BSX: For professional use only.

Ref. 859256, 859257, 859258, 859261, 859262, 859385, 859263, 859269, 859270, 859284: For layman use.

1.3. Company identification

Biosynex Swiss SA
Route de Rossemaison 100
CH-2800 Delémont – Switzerland

Tel.: 026 552 51 52
Fax: 026 552 51 54
Mail: info@biosynex.ch
Internet: www.biosynex.com

1.4. Emergency call

France: SAMU: 15

Switzerland: ambulance: 114

Number ORFILA: 01 45 42 59 59 (provides access to the list of poison centers and their phone number)

Swiss Center for toxicological information: Tox Info Suisse: 145 or 044 251 51 51

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]**

Hazard description:

Preparation not classified as dangerous according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Regarding Directive 1999/45/CE and Regulation 1272/2008 [CLP and European directive 67/548/EEC as modified], 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

N/A

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Product information:

In vitro diagnostics medical device. Test strip impregnated with dried chemical / biochemical reagents, buffer.

3.2. Hazardous components:

Device components:

Description	CAS Number	Einecs Number	Origin	Concentration in the final product	Hazard classification and risk phrase*
Products ingredients	Not listed and specified in 1272/2008	Not listed and specified in 1272/2008	Not listed and specified in 1272/2008	Not listed and specified in 1272/2008	Not listed and specified in 1272/2008
Sodium azide	26628-22-8	247-852-1	Chemical	0.02%	Aquatic Chronic 1; H300 + H310, H410, EUH032

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

Buffer components:

Description	CAS Number	Einecs Number	Origin	Concentration in the final product	Hazard classification and risk phrase*
Tris	77-86-1	201-064-4	Chemical	2.4%	Not listed and specified in 1272/2008
NaCl	7647-14-5	231-598-3	Chemical	1.2%	Not listed and specified in 1272/2008
Tween-20	9005-64-5	500-018-3	Chemical	0.5%	Not listed and specified in 1272/2008
1,2-Benzisothiazolin-	2634-33-5	220-120-9	Chimique	0.04%	Acute Tox.4, H302; Skin Irrit. 2, H315; Eye Dam. 1, H318;

3-One					Skin Sens. 1, H317; Aquatic Acute 1, H400
S9	26316-40-5	500-047-1	Chimique	0.5%	Not listed and specified in 1272/2008

Desiccant component:

Description	CAS Number	Einecs Number	Origin	Concentration in the final product	Hazard classification and risk phrase*
Silica gel	7631-86-9	231-545-4	/	99%	Not listed and specified in 1272/2008

*Risk phrases are developed in section 16.

3.3. Non-hazardous compounds:

Cassette: test strip, plastic housing

Test strip: 2019-nCoV antibody for labeling, 2019-nCoV antibody for coating, goat anti-mouse IgG for coating, heterophilic antibody, blocker-1, chloroauric acid, trisodium citrate, nitrocellulose membrane, PVC sheet

Buffer: NaCl, Tris, purified water, Tween-20, S9

Packaging: aluminum pouch with desiccant (for the cassette), plastic tube sealed with aluminum (for the buffer)

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. The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

After inhalation

N/A

After skin contact:

Wash with soap and water and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water.

After swallowing: If desiccant or other components are swallowed, seek medical attention.

5. FIRE FIGHTING MEASURES

Suitable extinguishing measures: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire-extinguishing methods suitable to surrounding conditions.

Extinguishing measures to avoid: No special measures

Special risk: In case of fire, the following can be released: Hazardous fumes and vapours, Carbon oxides (COx), Nitrogen oxides (NOx)

Special protective equipment for the firefighting : Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

Additional information: The device contains combustible materials.

6. ACCIDENTAL RELEASE MEASURES

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

6.1. Measure for individual protection:

Refer to Section 8 for protective measures when handling the spillage.

6.2. Measure for environmental protection:

Avoid release to the environment.

6.3. Measures for cleaning and waste collection:

Collect material and dispose of as waste according to Section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling:

Use individual protective equipment (lab coat and gloves) for biological compound handling.
Keep out of reach of children.

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:

Ref. SW40006 and SW40006_BSX: For Professional in-vitro use only.

Ref. 859256, 859257, 859258, 859261, 859262, 859263, 859269, 859270, 859284: For layman use.

See instructions for use.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION GEAR

8.1. Exposition cut off:

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

8.2. Individual exposure control:

General protective and hygienic measures

Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54/EC or US Regulation 29 CFR 1910.1030 for information on handling biohazardous materials. Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

Respiratory exposure

Required, if there is a risk of splashing or aerosol generation during sample handling.

Hand exposure

Disposable gloves (for sample handling). Material of gloves: latex / natural rubber. Penetration time of glove material: glove resistance is not critical as the gloves are intended to provide protection against sample material.

Eyes exposure

Safety glasses or face shield, where there is a risk of splashing during sample handling

Skin exposure

Lab coat

8.3. Environmental exposure control:

Collect cassettes in containers according to the official local regulation.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information:

	Device	Extraction buffer
Aspect	Solid (laminated test strip housed in a plastic holder)	Liquid
Color	white	Colorless
Odor	N/A	Odourless

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

pH	N/A
Boiling point/range	N/A
Melting point/range	N/A
Inflammability	N/A
Explosion limit	N/A
Ignition temperature	N/A
Self-ignition	Product is not self-igniting
Flash point	N/A
Danger of explosion	Product does not present an explosion hazard
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

N/A

10. STABILITY AND REACTIVITY

10.1. Chemical stability:

The product is stable in accordance with the recommended storage conditions.

10.2. Reactivity:

No dangerous reactions known.

10.3. Conditions to avoid:

Do not freeze

10.4. Incompatible materials:

N/A

10.5. Hazardous decomposition products:

No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Immediate effects on health:	After skin contact: No irritating effects anticipated. After eye contact: Contact with the chemicals impregnated in the test strip may cause mild irritation. Sensitization: No sensitizing effects known.
Acute toxicity	Quantitative data on the toxic effects of this product is not available.

Differed and chronic effects on health:	
Sensitization	no data available
Narcosis	no data available
Carcinogenicity	no data available
Mutagenicity	no data available
Toxicity for reproduction	no data available
Specific effects from particular compounds:	N/A

12. ECOLOGICAL INFORMATION

12.1. Toxicity

Quantitative data on the toxic effects of this product is not available.

12.2. Persistence and degradation

The device contains plastic and other components that are not readily degradable.

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:

Used devices and other contaminated materials should be disposed of as potentially biohazardous waste.

To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Unclean packaging - recommendation:

Disposal must be made in accordance with local waste management regulations.

Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

14. TRANSPORT INFORMATION

The conditions of shipping according to the notice: 2-30 ° C. Do not freeze.

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**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

No symbol is necessary based on our current knowledge.

16. OTHER INFORMATION**Text of H-codes and R-phrases mentioned in section 3**

✓ 1,2-Benzisothiazolin-3-One

EC n°1272/2008 Regulation	
Hazards	Description
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H317	May cause an allergic skin reaction
H400	Very toxic to aquatic life

The BIOSYNEX COVID-19 Ag BSS / BIOSYNEX COVID-19 Ag BSX is intended for in vitro diagnostic and destined to be used by health professionals only.

BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag / BIOSYNEX COVID-19 Ag BSS self-test is intended for in vitro diagnostic and destined to be used by layman users.

This test does not contain any hazardous substances beyond the limits. 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	2020-09-21	NA	Creation of the document
02	2021-02-15	1.2	Modification: Use on nasopharyngeal or nasal swab
03	2021-03-01	All	Addition of the new variants: BIOSYNEX COVID-19 Ag BSX (SW40006_BSXX) and BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag (859256, 859257, 859258)
04	2021-04-09	1.1	Addition of the references for BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag in 5 tests / kit: 859261, 859262, 859263
05	2021-04-13	All	Addition of the ref 859269 and 859270 (self-test versions for derogation to CE marking)
06	2021-05-17	1.1 3.2, 3.3	Addition of ref. 859284 Modification of part 3. following update/ corrections of the supplier
07	2022-03-23	1.1	Addition of new reference 859385
08	2022-10-27	1.1 and 7.3 1.3 3.2 and 3.3 16.	Update of test references Update of Biosynex Swiss SA postal address Modifications due to change of buffer composition Update of risk phrases following change of buffer composition