

SAFETY DATA SHEET

according to Regulation (EU) 2020/878 of 18 June 2020



COVID-19 (SARS-CoV-2) Antigen Test Kit

Date of compilation: 23.08.2021

Revision:

Page: 1/8

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name:

COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Saliva

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: For in vitro diagnostic use only (the product is used in vitro to qualitatively detect novel coronavirus antigen in a human nasal/ nasopharyngeal/ oropharyngeal swab or saliva)

1.3. Details of the supplier of the safety data sheet

BLIRT S.A.

ul. Trzy Lipy 3/1.38

80-172 Gdańsk

e-mail: office@blirt.eu

1.4. Emergency telephone number

European emergency number: 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

The product is not classified as hazardous according to Regulation (EC) 1272/2008

2.2. Label elements

Labeling according to Regulation (EC) No 1272/2008

Signal word ---

Pictograms ---

Hazard statements

Precautionary statements

General

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

Prevention

Response

Storage

Removal

SAFETY DATA SHEET

according to Regulation (EU) 2020/878 of 18 June 2020



COVID-19 (SARS-CoV-2) Antigen Test Kit

Date of compilation: 23.08.2021

Revision:

Page: 2/8

Supplemental information

2.3. Other hazards

This mixture does not contain substances that meet the criteria for PBT or vPvB in accordance with Annex XIII.

SECTION 3: Composition/information on ingredients

3.1. Substances

3.2. Mixtures

This product does not contain any hazardous components required to reporting in this section according to relevant regulations

Name of substance	Identifier	Classification 1272/2008	% weight
Sodium caseinate	Index: CAS: 9005-46-3 EC: 618-419-8 Registration No. REACH: --	---	1.0
Sodium chloride	Index: CAS: 7647-14-5 EC: -- Registration No. REACH: --	---	0.8689
Sodium phosphate dibasic dodecahydrate / Na ₂ HPO ₄ · 12 H ₂ O	Index: CAS: 10039-32-4 EC: 231-598-3 Registration No. REACH: --	---	0.7089
Tween-20	Index: CAS: 9005-64-5 EC: 500-018-3 Registration No. REACH: --	---	0.422
Ethyl p-hydroxybenzoate	Index: CAS: 120-47-8 EC: 204-399-4 Registration No. REACH: --	---	0.025
Water	Index: CAS: 7732-18-5 EC: 231-791-2 Registration No. REACH: --	---	Balance

Notes

The full meaning of the risk phrases H included in the section 16

[1] Specific concentration limits

[2] Substance for which there are national occupational exposure limit values

[3] Substance with a Union workplace exposure limit

SAFETY DATA SHEET

according to Regulation (EU) 2020/878 of 18 June 2020



COVID-19 (SARS-CoV-2) Antigen Test Kit

Date of compilation: 23.08.2021

Revision:

Page: 3/8

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

Not required under normal conditions of use.

Remove person to fresh air and keep comfortable for breathing.

If unconscious place in recovery position and seek medical advice.

If symptoms persist, call a physician.

Ingestion

Not required under normal conditions of use.

Rinse mouth with water.

If symptoms persist, call a physician

Eye contact

Not required under normal conditions of use.

Flush eyes with water as a precaution.

Remove contact lenses.

Protect unharmed eye.

If symptoms persist, call a physician

Skin contact

Not required under normal conditions of use.

Wash off with soap and plenty of water

4.2. Most important symptoms and effects, both acute and delayed

Symptoms: no description of any toxic symptoms.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

First aid supplies should be available on the workplace premises.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbondioxide

Use appropriate extinguishing media to extinguish fires in the vicinity.

Unsuitable extinguishing media

Do not direct dense jets of water onto the surface of a burning product.

5.2. Special hazards arising from the substance or mixture

Combustible.

Combustion products

Toxic thermal decomposition products, hazardous combustion gases as well as carbon monoxide and carbon dioxide (COx), may be generated during combustion.

Explosive mixtures

Not applicable

5.3. Advice for firefighters

Stay in danger area only with self-contained breathing apparatus.

Use standard firefighting methods for extinguishing chemical fires.

Use water to cool containers exposed to high temperatures, and if possible, remove them from the area affected.

Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

Use water spray jets to disperse vapours.

SAFETY DATA SHEET

according to Regulation (EU) 2020/878 of 18 June 2020



COVID-19 (SARS-CoV-2) Antigen Test Kit

Date of compilation: 23.08.2021

Revision:

Page: 4/8

Fire-fighter protective equipment

Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Full personal protective equipment.

Self-contained breathing equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not breathe vapors/mist. Evacuate the danger area, observe emergency procedures, consult an expert. Provide adequate ventilation. Avoid contact with eyes and skin. Wear appropriate protective equipment. Remove all sources of ignition. Keep all persons not equipped with personal protection equipment away.

6.2. Environmental precautions

Prevent environmental contamination.

Prevent product from entering soil, drains and waterways.

In case of serious contamination of soil, watercourse or sewage system, notify the appropriate authorities.

6.3. Methods and material for containment and cleaning up

Ventilate the area affected and avoid inhaling vapours.

Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully with liquid-absorbent material. Clean up affected area. Keep in suitable, closed containers for disposal. Place all contaminated mass collected in a substitute container and send it for disposal in accordance with the local regulations.

Comply with all applicable national and local regulations.

6.4. Reference to other sections

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

Advice on safe handling

Do not inhale reagents.

Avoid generation of vapors/aerosols.

For personal protection see section 8.

Dispose of rinse water in accordance with local and national regulations.

Recommendations for handling the mixture

Provide adequate ventilation.

Avoid contact with eyes and skin.

General industrial health and safety regulations

Do not eat, drink or smoke when using this product.

Wash hands thoroughly after handling.

Replace contaminated clothing.

Wash contaminated clothing before reusing.

Advice on protection against fire and explosion: normal fire protective measure

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Tightly closed. Keep in a well-ventilated place.

Keep locked up or in an area accessible only to qualified or authorized persons.

Store in according to instruction

Storage rooms must be ventilated.

Keep container tightly closed.

Store in a dry and cool place.

SAFETY DATA SHEET

according to Regulation (EU) 2020/878 of 18 June 2020



COVID-19 (SARS-CoV-2) Antigen Test Kit

Date of compilation: 23.08.2021

Revision:

Page: 5/8

Keep away from heat and ignition sources.
Do not store together with foodstuffs and animal feed.
Do not handle until all safety precautions have been read and understood.

7.3. Specific end use(s)

No data available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace

Name of the chemical agent	CAS	Limit values		Comments
		Long-term ppm	Short-term mg/m ³	
--	--	--	--	-

8.2. Exposure controls

Appropriate engineering controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment
Workstations and storage rooms must be well ventilated to keep the dust/vapour concentrations in the air below their limit values.

Individual protection measures

The type of protective equipment must be selected based on the quantity and concentration of hazardous substances in the given work environment.

Eye or face protection

Not required under normal conditions of use.

Skin protection / Hand protection

Not required under normal conditions of use.

Body protection

Not required under normal conditions of use.

Respiratory protection

Not required under normal conditions of use.

Environmental exposure controls

Do not discharge into drains and groundwater.

General health and safety guidelines

Follow good personal hygiene practices.

Wash hands before breaks and at the end of workday. When using do not eat or drink

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Diagnostic kit containing 1 bottles of liquid reagent.
Colour	Colorless / transparent
Odour	No odour
Melting point/freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability	Non flammable
Lower and upper explosion limit	No data available
Flash point	Does not flash

SAFETY DATA SHEET

according to Regulation (EU) 2020/878 of 18 June 2020



COVID-19 (SARS-CoV-2) Antigen Test Kit

Date of compilation: 23.08.2021

Revision:

Page: 6/8

Auto-ignition temperature	No data available
Decomposition temperature	No data available
pH	No data available
Kinematic viscosity	No data available
Solubility	Soluble in water
Partition coefficient n-octanol/water (log value)	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	No data available
Particle characteristics	No data available

9.2. Other information

Information with regard to physical hazard classes	No data available
Other safety characteristics	No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive under normal use, storage and transport conditions.

10.2. Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3. Possibility of hazardous reactions

Avoid direct sunlight exposure and low or high temperature.

10.4. Conditions to avoid

None known

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

Hazardous decomposition products formed under fire conditions.

- Carbon oxides

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

SAFETY DATA SHEET

according to Regulation (EU) 2020/878 of 18 June 2020



COVID-19 (SARS-CoV-2) Antigen Test Kit

Date of compilation: 23.08.2021

Revision:

Page: 7/8

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

Endocrine disrupting properties

No data

Other information

No data

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

12.2. Persistence and degradability

No data

12.3. Bioaccumulative potential

No data

12.4. Mobility in soil

No data

12.5. Results of PBT and vPvB assessment

This mixture does not contain substances that meet the criteria for PBT or vPvB in accordance with Annex XIII.

12.6. Endocrine disrupting properties

No data

12.7. Other adverse effects

No data

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of in accordance with all applicable local, state and federal regulations.

SECTION 14: Transport information

14.1. UN number or ID number

No data

14.2. UN proper shipping name

No data

14.3. Transport hazard class(es)

No data

Label no. :

No data

14.4. Packing group

No data

14.5. Environmental hazards

No data

14.6. Special precautions for user

No data

14.7. Maritime transport in bulk according to IMO instruments

No data

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Regulation (EC) No 1272/2008 (CLP) of the European Parliament and of the Council of 16 December 2008 on

SAFETY DATA SHEET

according to Regulation (EU) 2020/878 of 18 June 2020



COVID-19 (SARS-CoV-2) Antigen Test Kit

Date of compilation: 23.08.2021

Revision:

Page: 8/8

classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

- REGULATION (EC) No 1907/2006 OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
- COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

15.2. Chemical safety assessment

No data

SECTION 16: Other information

Full text of H-phrases mentioned in section 3:

Classification procedures according to Regulation (EC) 1272/2008

Classification based on producer's data.

Abbreviations and Acronyms:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

PP: Severe Marine Pollutant

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Note to readers

Producer/distributor/SDS maker did not test, certify, or approve the product described in this Material Safety Data Sheet (MSDS), and all information in this MSDS was provided by the supplier or was reproduced from publically available regulatory data sources. Producer/distributor/SDS maker makes no representations or warranties regarding the completeness or accuracy of the information in this MSDS and disclaims all liability in connection with the use of this information or the product described in this MSDS.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered by us to be dependable and is accurate to the best of our knowledge. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate protective mechanisms to prevent employee exposures, property damage or release to the environment. We assumed no responsibility for injury to the recipient or third persons, or for any damage to any property resulting from misuse of the product.

The product described in the safety data sheet should be stored and used in accordance with good industrial practices and in compliance with all applicable legal regulations.

The information contained in the safety data sheet is based on the current state of knowledge. It should not be considered a guarantee of any specific product properties.

We cannot make any representations or warranties regarding the accuracy or completeness of any information provided or the quality or specifications of any products, substances or mixtures discussed herein.

The user is responsible for creating conditions for the safe use of the product and for the consequences of its misuse.