

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Version 3.0

Revision Date : 08/09/2021

Print Date : 08/09/2021

SECTION 1: Identification of the product and of the company/undertaking

1.1 Product identifiers

Name : AffiDX SARS-CoV-2 Lateral Flow Antigen Test

Components: Lateral flow test cassette

Number : N/A

REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

1.2 Relevant identified uses of the product and uses advised against

Identified uses : The product is a rapid lateral flow assay for the qualitative, in vitro determination of SARS-CoV-2 Spike-1 (S1) in human nasal swab samples.

1.3 Details of the supplier of the safety data sheet

Company :

Mologic Ltd

Bedford Technology Park

Thurleigh

Bedfordshire

MK44 2YQ

UNITED KINGDOM

Telephone : +44 01234 780020

1.4 Emergency telephone number

Emergency Phone # : +44 01234 780020

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

None.

SECTION 3: Composition/information on ingredients

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Version 3.0

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3.1 Composition

The lateral flow cassette contains: 1. a nitro-cellulose membrane coated with antibodies and cellulose absorbent and 2. membrane pads pre-dried with detergent, Affimer® binders and coloured particle conjugates.'

SECTION 4: First aid measures

4.1 Description of first aid measures

Only after serious misuse of the lateral flow test cassette (by where it has been disassembled and the membrane exposed), are the following first aid measures warranted.

If inhaled

If breathed in, move person into fresh air. Consult a physician if required.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No information available. Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

In case of fire, hazardous fumes and vapours including carbon oxides (COx) and nitrogen oxides (NOx) can be released into the air.

5.3 Advice for firefighters

Wear full protective gear and self-contained respiratory device when extinguishing fires.

5.4 Further information

No data available

SECTION 6: Accidental release measures

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Version 3.0

Revision Date : 08/09/2021

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6.1 Personal precautions, protective equipment and emergency procedures

Isolate spillage and clean up immediately. Use personal protective equipment (refer to section 8).

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste (refer to section 13). Clean contaminated surface thoroughly.

6.4 Reference to other sections

Refer to sections 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Following Good Laboratory Practices (GLP). Avoid contact with skin, eyes, and clothes by wearing a lab coat and disposable gloves. Wash hands before and at the end of work. Do not eat, drink, or smoke in the laboratory.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place at 5-30°C. Avoid direct exposure to sunlight.

7.3 Specific end use(s)

Only use provided diluent for sample dilution. See Instructions For Use (IFU).

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with workplace control parameters

This product does not contain any quantity of material or element that exceeds the regulatory exposition cut-off level or that require monitoring in the workplace.

8.2 Exposure controls

Use personal protective equipment in the laboratory.

General protective and hygienic measures

Follow good laboratory practices (GLP). Wash hands before and after work.

Personal protective equipment

Eye/face protection

Use safety glasses.

Skin protection

Use disposable gloves and wear a lab coat.

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Respiratory protection

Respiratory protection not required.

Control of environmental exposure

Collect lateral flow test cassette in containers according to official local regulations.

SECTION 9: Physical and chemical properties

9.1 Lateral Flow Cassette

- a) Appearance Form: Solid; White test strip housed in plastic holder
- b) Odour: Odourless
- c) Odour Threshold: N/A
- d) pH: N/A
- e) Melting point: No data available
- f) Boiling point: No data available
- g) Flash point: Not applicable
- h) Evaporation rate: No data available
- i) Flammability: Not applicable
- j) Upper/lower flammability or explosive limits: Not applicable.
- k) Vapour pressure: No data available
- l) Vapour density: Not applicable
- m) Relative density: Not applicable
- n) Water solubility: Not applicable
- o) Partition coefficient: No data available
- p) Auto-ignition temperature: Not applicable
- q) Decomposition temperature: No data available
- r) Viscosity: Not applicable
- s) Explosive properties: No data available
- t) Oxidizing properties: No data available

9.2 Other safety information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Version 3.0

Revision Date : 08/09/2021

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No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No data available

Skin corrosion/irritation

Irritating effect

Serious eye damage/eye irritation

Irritating effect

Respiratory or skin sensitisation

Irritating effect

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Not available

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

SAFETY DATA SHEET

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Version 3.0

Revision Date : 08/09/2021

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No data available

12.3 Bioaccumulative potential

Does not accumulate in organisms.

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

After use, the product shall be handled routinely as contaminated waste. Such waste must be disposed of in accordance with all local laws and national regulations. To ensure compliance contact your local authorities for approved waste disposal information.

Packaging

Non-contaminated packaging materials can be recycled. Contact your local service providers for more information.

SECTION 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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SECTION 15: Regulatory information

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

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

International Chemical Weapons Convention

(CWC) Schedules of Toxic Chemicals and Precursors : Neither banned nor restricted

Restrictions on the marketing and use of certain dangerous substances and preparations : Neither banned nor restricted

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Neither banned nor restricted

Candidate List of Substances of Very High Concern for Authorisation : Neither banned nor restricted

SECTION 16: OTHER INFORMATION

Revision history:

Version	Change Author:	Change:	Date:
1	Mologic-SGC	Initial Creation	29 th Jan 2021
2	Mologic-PD	Minor modification to naming	3 rd Sept 2021
3	Mologic-PD	Modification to Section 1.2/7.3 word correction, 3.1 include Affimers	8 th Sept 2021

Indication of changes: N/A

Key literature references and sources for data: N/A

Further information

The above information is believed to be correct based on information at the time of writing but is not deemed to be all inclusive and should only be used as a guide. Mologic Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product.