

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 substance/mixture and of the company/undertaking

1.1 Substance identifiers

Name : AffiDx SARS-CoV-2 Antigen Lateral Flow Test - Sample buffer: 1x solution

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 substance or mixture and uses advised against

Identified uses : For extracting nasal swab samples and applying extracted sample to manufactured lateral flow assays.

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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

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Component	CAS-No	Weight %	Classification – Regulation (EC) No 1272/2008
Phosphate-buffered saline (PBS)	N/A	98.45% v/v	Non-hazardous
Bovine serum albumin (BSA)	9048-46-8	1% w/v	Non-hazardous
Tween-20	9005-64-5	0.5% v/v	Non-hazardous
ProClin 300	N/A	0.05% v/v	Eye Dam. 1; Acute Tox. 3; Acute Tox. 2; Skin Corr. 1C; Skin Sens. 1A; Aquatic Acute 1; Aquatic Chronic 4; H318, H301, H310, H330, H314, H317, H400, H413. Concentration limits: ≥ 0.6 %: Skin Corr. 1C, H314; 0.06 - < 0.6 %: Skin Irrit. 2, H315; 0.06 - < 0.6 %: Eye Irrit. 2, H319; ≥ 0.0015 %: Skin Sens. 1A, H317; ≥ 0.6 %: Eye Dam. 1, H318; M-Factor - Aquatic Acute: 100 - Aquatic Chronic: 100

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

First aider needs to protect him/herself. Show this material data sheet to the doctor in attendance

If inhaled

Remove to fresh air. Immediate medical attention required

In case of skin contact

Remove all contaminated clothing. Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention required

In case of eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses. Immediate medical attention required

If swallowed

Make victim drink water (two glasses at most), avoid vomiting (risk of perforation). Call a doctor/physician immediately. Do not attempt to neutralise

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 data available

SECTION 5: Firefighting measures

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5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x), Sulfur oxides, Hydrogen chloride gas

5.3 Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing

5.4 Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent and neutralising material. Dispose of properly. Clean up affected area

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Do not inhale substance/mixture. For precautions see section 2.2..

7.2 Conditions for safe storage, including any incompatibilities

Ideal storage at 5-30 °C. Keep container tightly closed.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure controls

Appropriate engineering controls

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands after working with substance

Personal protective equipment

Eye/face protection

Wear safety glasses with side shields (or goggles) (European standard - EN 166)

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU)2016/425 and the standard EN 374 derived from it.

Body Protection

Protective clothing

Respiratory protection

Required when vapours/aerosols are generated. Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Recommended half mask:- Valve filtering: EN405; or; Half mask: EN140; plus filter, EN 141

Control of environmental exposure

Prevent product from entering drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- a) Appearance Form: liquid; Colour: Yellow
- b) Odour: Odourless
- c) Odour Threshold: No data available
- d) pH 7-8
- 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

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- 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: No data available
- 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

None known, based on information available.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents, Reducing agents, Amines, Mercaptans

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NO_x), Sulfur oxides, Hydrogen chloride gas

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 862 mg/kg

LD50 Dermal - Rabbit - 2,800 mg/kg

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Skin corrosion/irritation

Skin - Rabbit

Result: Corrosive

Mixture causes burns.

Serious eye damage/eye irritation

Eyes - Rabbit

Result: Corrosive to eyes

Mixture causes serious eye damage. Risk of blindness

Respiratory or skin sensitisation

- Guinea pig

Result: May cause sensitization by skin contact.

Mixture may cause an allergic skin reaction

Germ cell mutagenicity

No additional information

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

Acute oral toxicity - If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach.

Acute inhalation toxicity - mucosal irritations, Cough, Shortness of breath, Possible damages: damage of respiratory tract

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Not available

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12: Ecological information

12.1 Toxicity

No data available

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12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste material must be disposed of in accordance with the national and local guidance. No mixing with other waste. Handle uncleaned containers like the product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: - IMDG: - IATA: -

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

SECTION 15: Regulatory information

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

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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 2	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.