

Clarity COVID-19 Antigen Test

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Date of issue: 09/16/2020

Version: 1.0

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

1.1. Product identifier

Product name : Clarity COVID-19 Antigen Test

Product code : CLA-COV19-AG20

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For in vitro diagnostic use

Use of the substance/mixture : For professional use only

Product is not intended for consumer use.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Clarity Diagnostics

1701 Green Road Suite A

Deerfield Beach, Florida 33064

USA

Tel: +1-561-288-9028 (Eastern time, USA)

Email: techsupport@claritydiagnostics.com

1.4. Emergency telephone number

Emergency number : +1-561-922-4047 (Eastern time, USA)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD] Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] No

labelling applicable

2.3. Other hazards

No additional information available

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SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Comments : In vitro diagnostic medical device.
Test strip impregnated with dried chemical reagents.

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The strip, consisting of an inert membrane and pad material impregnated with chemical reagents in dry form, is housed in plastic casing and placed in a foil pouch containing desiccant (silica gel bag).

The weight percent of the chemical components impregnated onto test strip are respectively far less than 0.1% which does not meet EU hazardous material Regulation (EC) No. 453/2010.

The table below presents the information on hazardous substance:

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Silica, amorphous, precipitated and gel substance with national workplace exposure limit(s) (AT, BE, BG, FI, PL)	(CAS No) 112926-00-8 (EC no) 601-214-2	100	Not classified

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium Azide	(CAS No) 26628-22-8-00-8 (EC no) 247-852-1	<0.1%	Not classified

Full text of R- and H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Inhalation is unlikely a route of exposure at ambient temperature. Allow breathing of fresh air. Allow the victim to rest.

First-aid measures after skin contact : In case of fire: Risk of thermal burns on contact with molten product. After contact with the molten product, cool rapidly with cold water. Do not attempt to remove the molten material from the skin. Burns caused by molten material must be treated clinically.

First-aid measures after eye contact : if dust or fume contacts the eyes,. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a poison center.

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/injuries after skin contact : In case of fire: Risk of thermal burns on contact with molten product. Burns caused by molten material must be treated clinically.

Symptoms/injuries after eye contact : If user operation generates fumes: Vapor irritates eyes and cause tearing.

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

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No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use fire-extinguishing media appropriate for surrounding materials. Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

- Firefighting instructions : Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protective equipment for firefighters : Do not enter fire area without proper protective equipment, including respiratory protection.
- Other information : Avoid all eye and skin contact and do not breathe vapour and mist.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : The low volatility of this product does not require ventilation. However depending on the condition an adequate ventilation might be required.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Store away from other materials. Avoid creating or spreading dust. Avoid contact with components within this kit. Dispose of contents/container to comply with applicable local, national and international regulations. Consult the appropriate authorities about waste disposal. Follow good laboratory practice and occupational hygiene.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Obtain special instructions before use. Read label before use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid contact with components within this kit. This kit should be handled only by qualified clinical or laboratory trained employees. For In Vitro Diagnostic Use Only – Not for use by general public. Follow good laboratory practice and occupational hygiene.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store at room temperature, not above 30°C and not below 2°C. Keep container closed when not in use.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : A washing facility/water for eye and skin cleaning purposes should be present. Ensure adequate ventilation.

Personal protective equipment : Avoid all unnecessary exposure. Gloves. Protective goggles. Protective clothing. For certain operations, additional Personal Protection Equipment (PPE) may be required.



Hand protection : Wear protective gloves

Eye protection : Chemical goggles or safety glasses

Respiratory protection : Wear appropriate mask

Other information : Do not eat, drink or smoke during use. Follow good laboratory practice and occupational hygiene.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Cassette : Solid	Extraction Buffer Liquid
Appearance	: The strip, consisting of an inert membrane and pad material impregnated with chemical reagents in dry form, is housed in plastic casing and placed in a foil pouch containing desiccant (silica gel bag)	The liquid contained in firmly closed extraction buffer tube
Colour	: White	Clear
Odour	: Odourless	Odourless
Odour threshold	: No data available	No data available
pH	: No data available	7.2 ~ 7.4
Relative evaporation rate (butyl acetate=1)	: No data available	No data available
Melting point	: No data available	No data available
Freezing point	: No data available	No data available
Boiling point	: No data available	100°C
Flash point	: No data available	No data available
Auto-ignition temperature	: No data available	No data available
Decomposition temperature	: No data available	No data available
Flammability (solid, gas)	: Non flammable	No data available
Vapour pressure	: No data available	No data available
Relative vapour density at 20 °C	: No data available	No data available
Relative density	: No data available	No data available
Solubility	: No data available	No data available
Log Pow	: No data available	No data available

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Viscosity, kinematic	: No data available	No data available
Viscosity, dynamic	: No data available	No data available
Explosive properties	: No data available	No data available
Oxidising properties	: No data available	No data available
Explosive limits	: No data available	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified
Based on available data, the classification criteria are not met

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified
Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

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Based on available data, the classification criteria are not met Specific target organ toxicity (single exposure) : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified

Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Based on available data, the classification criteria are not met

Potential Adverse human health effects and : Based on available data, the classification criteria are not met. symptoms

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

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Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Used devices and other contaminated materials should be disposed of as potentially bio-hazardous waste. Consult the appropriate local waste disposal expert about waste disposal.

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Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

No known transport restrictions

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name : Not applicable

14.3. Transport hazard class(es)

Transport hazard class(es) : Not applicable

14.4. Packing group

Packing group : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No additional information available.

15.1.2. National regulations

No additional information available.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out
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SECTION 16: Other information

Sources of Key data : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on 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.

Other information : None.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product