

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH) and Regulation (EU) No. 453/2010



Product Name: DIAQUICK COVID-19 Ag Cassette

Version: 01

Date: September 10, 2020

1. Identification of the substance/preparation and of the company/undertaking

1.1. Identification of the substance or preparation

DIAQUICK COVID-19 Ag Cassette

The reagent is part of the following catalogue numbers:

Z20401CE

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

General use: Laboratory reagent for in-vitro diagnostics in human samples

1.3. Details of the supplier of the safety data sheet

Manufacturer:

Dialab Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H

Address: Hondastrasse, Objekt M55, IZ-NOE Sued, A-2351 Wr. Neudorf, Austria

Telephone / E-mail: +43 (0)2236 660910-0 / office@dialab.at

1.4. Emergency telephone number

Vienna General Hospital, Toxication Centre, phone: +43-(0)1-4064343

2. Hazards identification

2.1. Classification of the substance or mixture:

Classification according to Directive 1272/2008/EC:

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

2.2. Label elements:

Labelling (1272/2008/EC):

None

2.3. Other hazards

None

3. Composition / information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Chemical characterisation:

In vitro diagnostic medical device. Test strip impregnated with dried chemical/ biochemical reagents.

Dangerous components:

Cassette:

Component	CAS No.	EINECS No.	Classification	Concentration
<i>Product ingredients</i>	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

Buffer:

Component	CAS No.	EINECS No.	Classification	Concentration
<i>Sodium azide</i>	26628-22-8	247-852-1	Acute Tox. 2; Acute Tox. 1; Aquatic Acute 1; Aquatic Chronic 1; H300 + H310, H410, EUH032	0.09%
<i>NaCl</i>	7647-14-5	231-598-3	Not listed in 1272/2008	1%
<i>Tris</i>	77-86-1	201-064-4	Not listed in 1272/2008	2%
<i>Purified water</i>	7732-18-5	215-185-5	Not listed in 1272/2008	96.91%

3.3. Other information

Each device is packaged in a foil pouch.

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4. First aid measures

4.1. Description of first aid measures

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 or there is exposure to the buffer.

After skin contact:

Wash with soap and water and rinse thoroughly.

After eye contact:

Rinse opened eye for several minutes under running water.

After ingestion:

If desiccant, buffer or other components are swallowed seek medical attention.

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

Non known.

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

Non known.

5. Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

In case of fire, the following can be released: Hazardous fumes and vapours, Carbon oxides (CO_x), Nitrogen oxides (NO_x).

5.3. Advice for firefighters

Protective equipment:

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

Addition information:

The device contains combustible materials.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

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

7. Handling and storage

7.1. Precautions for safe handling

Keep out of reach of children.

7.2. Conditions for safe storage, including any incompatibilities

Store in the original container at 2-30°C.

No special requirements to be met by storerooms and receptacles.

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8. Exposure controls/personal protection

8.1. Control parameters

Ingredients with limit values that require monitoring in the workplace:

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

8.2. Exposure controls

Appropriate engineering controls:

None.

Personal protective equipment:

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 1910.10.1030 for information on handling biohazardous materials.

Wash hands before breaks and at the end of the work. Clean work areas with hypochlorite or other disinfecting agent.

Respiratory protection:

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

Protection of hands:

Disposable gloves (for sample handling).

Material of gloves:

Latex/ natural rubber.

Penetration time of glove material:

Glove resistant is not critical as the gloves are intended to provide protection against the sample material.

Eye protection:

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

Body protection:

Lab coat.

Environmental exposure controls:

None.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Cassette:

Form: The device is an article containing solid components.

Appearance: Laminated test strip, which may be housed in a plastic holder.

Odour: Odourless

Flash point: Not applicable

Self-igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

Buffer:

Form: Liquid

Appearance: Colourless

Odour: Odourless

Flash point: Not applicable

Self-igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

9.2. Other information

None.

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10. Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

No dangerous decomposition products known.

11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity:

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

Primary effects:

After skin contact:

No irritating effects anticipated.

After eye contact:

Contact with the chemicals impregnated in the test strip may cause mild irritation.

Sensitisation:

No sensitising effects known.

11.2. Further information

No further information.

12. Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

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

12.3. Bioaccumulative 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

None.

12.7. Other information

None.

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13. Disposal considerations

13.1. Waste treatment methods

Product:

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.

European waste catalogue:

18 01 03 waste whose collection and disposal are subject to special requirements in order to prevent infection.

Packaging:

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

14.1. UN number

ARD/RID, IMDG, IATA-DGR, ICAO-TI, US DOT: Not regulated for transport.

14.2. UN proper shipping name

ARD/RID, IMDG, IATA-DGR, ICAO-TI, US DOT: Not regulated for transport.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Marine pollutant – IMDG: No.

14.6. Special precautions for user

No dangerous goods in sense of these transport regulations.

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

No data available.

15. Regulatory information

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

Labelling according to EU guidelines:

Safety data sheet available for professional user on request.

Note:

The preparation is exempt from the above labelling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

US Hazard warnings according to 16 CFR 1600 and ANSI Standard Z129.1:

Not required.

Chemical inventory listings relevant to US regulations:

IARC:	None of the ingredients is listed.
NTP:	None of the ingredients is listed.
ACGIH:	None of the ingredients is listed.
OSHA:	None of the ingredients is listed.
EPA:	None of the ingredients is listed.

Californian Proposition 65:

Chemicals known to cause cancer:	None of the ingredients listed.
Chemicals known to cause reproductive toxicity:	None of the ingredients listed.

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SARA:

Section 355 (extremely hazardous substances):	None of the ingredients listed.
Section 313 (specific toxic chemical listings):	None of the ingredients listed.

15.2. Chemical Safety Assessment

For this product a chemical safety assessment is not required.

16. Other information

Reason of Change:

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Contact person: see section 1.3

Dialab GmbH provides the information in this data sheet in good faith, declaring it is up to date at time of revision. However, this document is intended only as a guide for professional use, according to the intended purposes of the product. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

The product is for in vitro diagnostic use only by trained personnel.