

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	File No: TF- COVID-19	
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Appendix I

Material Safety Data Sheets

**COVID-19 IgG/IgM Rapid Test Cassette
(Whole Blood/Serum/Plasma)**

Zhejiang Orient Gene Biotech Co., Ltd

MATERIAL SAFETY DATA SHEET OF
COVID-19 IgG/IgM Rapid Test Cassette
(Whole Blood/Serum/Plasma)

According to REACH Regulation (EC) No. 1907/2006, Annex II

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

Identification of the substance or preparation

Trade name: **COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)**

Reference No.: GCCOV-402a

Use of the substance/preparation: In vitro diagnostic medical device. For professional use only.

Company/undertaking identification:

ZheJiang Orient Gene Biotech Co.,Ltd

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Further information obtainable from: For further information, contact your local distributor/supplier.

2. Hazards identification

Hazard description:

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

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200:

As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

3. Composition/information on ingredients

Chemical characterisation

**COVID-19 IgG/IgM Rapid Test Cassette
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Description:

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

Dangerous components:

Component	CAS No.	EINECS No.	Classification	Concentration
Sodium azide	26628-22-8	247-852-1	Acute Tox. 2; Acute Tox. 1; Aquatic Acute 1; Aquatic Chronic 1; H300 + H310, H410, EUH032	0.02%
Other products ingredients	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

Additional information:

Each device is packaged in a foil pouch.

For the wording of the listed risk phrases refer to section 16.

4. First-aid measures

General Information:

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.

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 or other components are swallowed seek medical attention.

5. Fire-fighting measures

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire-extinguishing methods suitable to surrounding conditions.

Special hazards caused by the substance, its products of combustion or resulting gases:

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

Protective equipment:

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

Additional information:

The device contains combustible materials.

6. Accidental release measures

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Page 4 of 7**Person-related safety precautions:**

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

Measures for environmental protection:

Avoid release to the environment.

Measures for cleaning/collecting:

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

7. Handling and storage**Information for safe handling:**

Keep out of reach of children.

Storage:

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

Requirements to be met by storerooms and receptacles:

No special requirements.

8. Exposure controls/personal protection**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.

Additional information:

The lists valid during the creation of this MSDS were used as a basis for this assessment.

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 1910.1030 for information on handling biohazardous materials.

Wash hands before breaks and at the end of 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 resistance 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

9. Physical and chemical properties

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General Information

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.

10. Stability and reactivity

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

Materials to be avoided: None

Hazardous reactions: No dangerous reactions known.

Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological information**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.

12. Ecological information**Environmental Toxicity:**

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

Persistence and Degradability:

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

13. Disposal considerations**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 wastes whose collection and disposal is 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

Land transport ADR/RID (cross-border)

Not regulated for transport.

US DOT Transport Regulations:

Not regulated for transport.

Maritime transport IMDG:

Not regulated for transport.

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

Not regulated for transport.

15. Regulatory information

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:

Carcinogen listings

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 is listed.

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

SARA

Section 355 (extremely hazardous substances): None of the ingredients is listed.

Section 313 (specific toxic chemical listings): None of the ingredients is listed.

16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Relevant R-phrases

22 Harmful if swallowed.

41 Risk of serious damage to eyes.

