# SAFETY DATA SHEET

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|---|---|
| **Catalog Number:** | WL03P0001 |
| **Product Name:** | WELLlife™ COVID-19 Antigen Home Test; |

**This document contains SDS for the following kit components:**

| **Pages** | **Component Name:** |
|---|---|
| 2-6 | The test cassette consists of test strip and plastic cassette. The test strip includes: nitrocellulose membrane, sample pad, conjugated pad, absorbent paper and PVC board.<br>The individual sealed pouch consists of 1 Test cassette/strip and 1 desiccant pouch. |

**Note:**
This SDS is for Test Cassette of WELLlife™ COVID-19 Antigen Home Test only.

## 1. Identification of Substance:

**Product Name:**
WELLlife™ COVID-19 Antigen Home Test (Catalog # WL03P0001)

**Application of the Substance / the Preparation:**
Component of WELLlife™ COVID-19 Antigen Home Test (catalog # WL03P0001). For use in the qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19. For *in vitro* diagnostic use only. For Over the Counter (OTC) Use.

**Supplier:**

**Guangzhou Wondfo Biotech Co., Ltd.**
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Huangpu District, 510663 Guangzhou, P.R.China
Tel: (+86) 400-830-8768
**Emergency Information:** sales@wondfo.com.cn


## 2. Hazards Identification

**Information Pertaining to Particular Dangers for Man and Environment:**
The preparation is not classified as dangerous according to Regulation (EC) No 1272/2008

**Classification System:**
The classification is in line with current EC (European Community)-directives. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

## 3. Composition/Information on Ingredients

**Chemical Characterization**

**Description:**
*In vitro* diagnostic reagent. Aqueous preparation. The device contains:

| Composition | Application | Weight % |
|---|---|---|
| Glass Fiber (CAS# 65997-17-3) | Sample pad and conjugated pad | 0.29518032% |
| Absorbent Paper/Cellulose (CAS# 9004-34-6) | Absorbent pad | 0.7872% |
| $HAuCl_4$/Tetrachloroauric acid (CAS# 16903-35-8) | Colloid gold | 0.00001968% |
| Nitrocellulose Membrane (CAS# 9004-70-0) | Coating membrane | 0.19678032% |
| PVC Board (CAS# 9002-86-2) | Backer, support various parts, | 4.2312% |

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| | laminate into a discrete unit | |
| Cassette Cover/Polystyrene (CAS# 9003-53-6) | Hold and protect a strip | 94.1944% |
| Sticky Tape/BOPP (CAS# 128625-52-5) | Keeping the test strips structurally sound | 0.08856% |
| Sticky Tape/Acrylic Adhesive (CAS# 9010-77-9) | Keeping the test strips structurally sound | 0.20664% |
| Antibody Mix (CAS# 89957-37-9) | Control line and Test line Antibody | 0.00001968% |

**Product Use:** *In Vitro* diagnostic use only

**Dangerous Components:**
The preparation does not contain reportable quantities of hazardous components.

## 4. First Aid Measure

- **Skin Contact:** Remove from source of exposure. Wash affected area with soap and water. If signs of infection occur, seek medical attention.
- **Eye Contact:** Remove from source of exposure, immediately flush skin with cool water. Obtain medical attention if needed or if irritation or other symptoms develop.

**Ingestion:** If irritation or signs of toxicity occur, seek medical attention.

## 5. Fire-fighting Measures

**Suitable Extinguishing Media:**
Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

**Unsuitable Extinguishing Media:**
Unknown.

**Standard Protective Equipment and Precautions for Firefighters:**
Wear self-contained breathing apparatus for firefighting if necessary.

## 6. Accidental Release Measures

**Reference to other sections**
For disposal, see section 13.

## 7. Handling and Storage

**Handling:**
Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after

handling.

**Storage:**
Store at 2℃～30℃. See Section 10.

## 8. Exposure Controls/Personal Protection

**Components with Limit Values that Require Monitoring at 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 that were valid during the compilation were used as basis.

**Personal Protective Equipment (PPE):**

**General Protective and Hygienic Measures:**
Adhere to good laboratory practices (GLP).
Wash hands during breaks and at the end of the work.

**Breathing Equipment:**
Not necessary, if room is well-ventilated.

**Protection of Hands:**
The gloves serve to protect the user against splashes. For safety reasons they should be changed immediately after wetting.
Since the product is in fact a preparation out of several substances, no specific information can be given on the permeation breakthrough time. The choice of suitable gloves depends not only on the material, but also on other quality features and must, therefore, be checked with the respective manufacturer. As far as we know, disposable gloves, among other things out of nitriles, are suitable. Nevertheless, this recommendation is not intended to replace a suitability test, which is essential and must be carried out under the respective conditions of use.

**Eye Protection:** Safety glasses recommended during refilling.

## 9. Physical and Chemical Properties

Physical state: Cassette
Odor: Odorless
Solubility: Insoluble in water
Specific Gravity: Not available
Boiling Point: Not available
Melting Point: Not available
Fresh Point: Not applicable
Flammable Limits: Not applicable
Auto Ignition Temperature: Not applicable

## 10. Stability and Reactivity

**Chemical Stability:** Stable under ordinary conditions of use and storage. See Section 7.
**Material to be Avoid:** None know
**Hazardous Polymerization:** Will not occur

## 11. Toxicological Information

**Acute Toxicity:** Quantitative data on the toxic effects of this product is not available.
This product is used in vitro. No sensitizing effect known.

## 12. Ecological Information

· **General Notes:** Generally not hazardous for water.

## 13. Disposal Considerations

**General Notes:**
In general laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations.

**Packaging:**
Disposal must be made in accordance with the local waste management regulations.
Contaminated packaging must be disposed of in the same manner as the product.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

## 14. Transport Information

**Land Transport ADR/RID (Cross-Border)**
- ADR/RID-GGVS/E Class: -
- Remarks: not restricted

**Air Transport ICAO-TI and IATA-DGR:**
- ICAO/IATA Class: -
- Remarks: not restricted

## 15. Regulatory Information

**Designation according to EC Guidelines:**
No marking required.

## 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.