



**Hangzhou Clongene Biotech Co., Ltd.**

No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou, 311121, China

Tel: +86-571-88262120  
Fax: +86-571-88261752

Web: www.clongene.com  
Email: marketing@clongene.com

**MATERIAL SAFETY DATA SHEET**

**SECTION 1 IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY**

**1.1 Product identifier**

CLUNGENE COVID-19 Antigen Rapid Test

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

**Relevant identified uses:** For in vitro diagnostic use and for use by medical professionals or trained operators who are proficient in performing lateral flow tests

**Uses advised against:** Any non-intended use

**1.3 Details of the supplier of the safety data sheet**

**Manufacturer:** Hangzhou Clongene Biotech Co., Ltd.

**Address:** No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou, 311121, China

**Telephone number:** 0086-571-88262120

**Fax number:** 0086-571-88261752

**E-mail address:** [css@clongene.com](mailto:css@clongene.com)

**1.4 Emergency telephone number**

Emergency number: 0086-571- 88262120

杭州隆基生物技术有限公司  
HANGZHOU CLONGENE BIOTECH CO., LTD.

杭州  
HANGZHO

**SECTION 2 HAZARDS IDENTIFICATION**

**2.1 Classification of the substance or mixture**

**Regulation (EC) No. 1272/2008**

This mixture is not classified as hazardous in accordance with REGULATION (EU) No. 1272/2008.

**2.2 Label elements**

Additional advice on labeling

Labeling according to Regulation (EC) No. 1272/2008 [CLP]: none

**2.3 Other hazards**

The substance or mixture used in the product do not meet the PBT (Substances that are potentially Persistent, Bioaccumulative and Toxic)/vPvB (Substances that are potentially Very Persistent and Very Bioaccumulative) criteria according to REACH(Registration, Evaluation, Authorisation and Restriction of Chemicals), annex XIII.

No risks worthy of mention. Please observe the information on the safety data sheet at all times.

**SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS**

**Chemical characterization: Mixtures**

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II.

**SECTION 4 FIRST AID MEASURES**

**4.1 Description of first aid measures**

**General advice:** In case of accident or unwellness, seek medical advice immediately. Show this safety data sheet (SDS) to the doctor in attendance.

**Inhalation:** In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, seek medical advice.

**Ingestion:** Rinse mouth thoroughly with water. Let water be drunk in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.



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**Skin Contact:** Wash off with soap and plenty of water, Seek medical attention if necessary.

**Eye Contact:** Rinse thoroughly with running water, saline or Eye washing liquid, Seek medical attention if necessary.

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

No additional information available.

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

Treat symptomatically.

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## SECTION 5 FIREFIGHTING MEASURES

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### 5.1 Extinguishing Media

Water, carbon dioxide, multipurpose dry chemical or halon-fire extinguisher.

### 5.2 Special Protective Equipment for Fire-fighter

Wear self-contained breathing apparatus for firefighting if necessary.

### 5.3 Advice for Fire Fighters

Take comprehensive protective measures.

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## SECTION 6 ACCIDENTAL RELEASE MEASURES

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### 6.1 Personal precautions, protective equipment and emergency procedures

Safe handling: see section 7

Personal protection equipment: see section 8

### 6.2 Environmental Precautions

Discharge into the environment must be avoided.

### 6.3 Methods and material for containment and cleaning up

Wipe up with absorbent material (e.g. cloth, paper). Pick up and transfer to properly labeled containers.

### Reference to other sections

None.

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## SECTION 7 HANDLING AND STORAGE

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### 7.1 Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures: Always wash hands after handling the product.

### 7.2 Conditions for safe storage, including any incompatibilities

Store at 4-30°C in original sealed package.

### 7.3 Specific end use(s)

None.

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## SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

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### 8.1 Control parameters

**Exposure Limits values:** There are no established exposure limits for this product, nor indicated for any ingredients.

### 8.2 Exposure controls

**Engineering Controls:** No special measures are necessary.

**Protective and hygiene measures:** Wash hands before breaks and after use.

**Eye/Face Protection:** Wear safety glasses with side shields (or goggles).

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**Respiratory Protection:** With correct and proper use, and under normal conditions, breathing protection is not required.

**Skin Protection:** Wear protective clothing.

**Hand Protection:** Chemical resistant gloves.

**Environmental exposure controls:** No special precautionary measures are necessary.

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## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

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### 9.1 Information on basic physical and chemical properties

**Appearance, Color, Odor:** Flat, white plastic housing containing white, narrow membrane test strip; odorless.

**pH:** No data available.

**Boiling Point:** No data available.

**Melting Point:** No data available.

**Flash Point:** No data available.

**Ignition temperature:** No data available.

**Low Explosion Limit:** No data available.

**High Explosion Limit:** No data available.

**Vapor pressure (kPa):** No data available.

**Vapor density (air = 1):** No data available.

**Relative density (water = 1):** No data available.

**Solubility (mg/L):** No data available.

**Octanol/water partition coefficient:** No data available.

**Auto-ignition temperature (°C):** No data available.

**Decomposition temperature (°C):** No data available.

**Viscosity:** No data available.

**Others: Resistance value:** No data available.

### 9.2 Other information

No additional information available.

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## SECTION 10 STABILITY AND REACTIVITY

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### 10.1 Reactivity

Under norm conditions of storage, it will not react on its own. The product is non-reactive under normal conditions of use, storage and transport.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No data available.

### 10.4 Incompatible materials

Strong oxides, strong acids, strong bases.

### 10.5 Hazardous decomposition products

Under norm conditions of storage and use, hazardous decomposition products should not be produced.

### 10.6 Conditions to Avoid

Excessive heat, direct sunlight.



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**SECTION 11 TOXICOLOGICAL INFORMATION**

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**11.1 Information on toxicological effects**

**Acute Toxicity:** No data available.

**Serious eye damage irritation:** No data available.

**Skin corrosion/irritation:** No data available.

**Respiratory or skin sensitisation:** No data available.

**STOT single/repeated exposure:** No data available.

**Carcinogenicity:** Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:** No data available.

**Chronic Toxicity (Target Organ Effects):** No data available.

**Reproductive toxicity:** No data available.

**Aspiration hazard:** No data available.

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**SECTION 12 ECOLOGICAL INFORMATION**

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**12.1 Toxicity**

No data available.

**12.2 Persistence and Degradability**

No data available.

**12.3 Bio accumulative potential**

No data available.

**12.4 Mobility in soil**

No data available.

**12.5 Result of PBT and vPvB assessment**

No data available.

**12.6 Further Information on Ecology**

No data available.

**12.7 Other adverse effects**

No data available.

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**SECTION 13 DISPOSAL CONSIDERATIONS**

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**13.1 Waste treatment methods**

**Disposal considerations:** Dispose of waste and residues in accordance with local authority requirements.

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**SECTION 14 TRANSPORT INFORMATION**

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**IMDG/IMO**

**14.1 UN-Number:** Not regulated.

**14.2 Proper Shipping Name:** Not regulated.

**14.3 Hazard Class:** Not regulated.

**14.4 Packing Group:** Not regulated.

**Description:** Not applicable.

**14.5 Marine Pollutant:** None.

**14.6 Special Provisions:** None.

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** No information

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available.

**RID**

**14.1 UN-Number:** Not regulated.

**14.2 Proper Shipping Name:** Not regulated.

**14.3 Hazard Class:** Not regulated.

**14.4 Packing Group:** Not regulated.

**Description:** Not applicable.

**14.5 Environmental hazard:** None.

**14.6 Special Provisions:** None

**ADR**

**14.1 UN-Number:** Not regulated.

**14.2 Proper Shipping Name:** Not regulated.

**14.3 Hazard Class:** None.

**14.4 Packing Group:** Not regulated.

**14.5 Environmental hazard:** None.

**14.6 Special Provisions:** None.

**IATA/ICAO**

**14.1 UN-Number:** Not regulated.

**14.2 Proper Shipping Name:** Not regulated.

**14.3 Hazard Class:** Not regulated.

**14.4 Packing Group:** Not regulated.

**Description:** Not applicable.

**14.5 Environmental hazard:** None.

**14.6 Special Provisions:** None.

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**SECTION 15 REGULATORY INFORMATION**

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**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture  
Candidate List of Substances of Very High Concern for Authorization**

Product does not contain listed SVHC (Substances of Very High Concern) substances > 0,1 % according to REGULATION (EU) No. 1907/2006 Article 59 (REACH).

**15.2 Chemical Safety Assessment**

No information available.

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**SECTION 16 OTHER INFORMATION**

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**Version:** 2.0

**Revision Information:** No data available.

**Further Information:** No data available.

**General Disclaimer:**

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Hangzhou Clongene Biotech Co., Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product.

