杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co.,Ltd.
No.1 Yichuang Road, Yuhang Sub-district,Yuhang District,Hangzhou ,311121,China
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MATERIAL SAFETY DATA SHEET

SECTION 1 IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

Product name: COVID-19 Antigen Rapid Test Cassette

Brand: CLUNGENE

Manufacturer: Hangzhou Clongene Biotech Co., Ltd.

Address: NO.1 YICHUANG ROAD,YUHANG SUB-DISTRICT, YUHANG DISTRICT, HANGZHOU , 311121, CHINA

Telephone number: 0086-571-88262113

Fax number: 0086-571-88261752

E-mail address: css@clongene.com

SECTION 2 HAZARDS IDENTIFICATION

Hazard classification according to GHS: The product is not dangerous and it has no hazardous classification.

Label elements: Hazard pictograms: None**, Signal word:** None**.**

Hazard statements: None

Precautionary statements: Keep container tightly closed. IF ON SKIN Wash with soap and water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Characterization: Substances

List of ingredients

Component	CAS #	% W/V
Sample pad	N/A	<0.1%
Colloidal gold dye pad	N/A	<0.1%
Plastic card board	N/A	96.50%
PVC	9002-86-2	>2.8%
Acrylic Acrylate	7910-7	<1%
Nitrocellulose	9004-70-0	>0.008%
anti-SARS-CoV-2 nuclenocapsid protein monoclonal antibody	N/A	<3%
SARS-CoV-2 nuclenocapsid protein monoclonal antibody	N/A	<3%
Disodium hydrogen phosphate	10039-32-4	<0.5%
Sodium dihydrogen phosphate	13472-35-0	<0.1%
NaCl	7647-14-5	<1%
Water	7732-18-5	> 95%
Cellulose microcrystalline	113669-95-7	>0.5%

Fiberglass	65997-17-3	>0.24%
Silica gel	112945-52-5	>0.13%
Poly(Ethylene Terephthalate)	25038-59-9	N/A
Aluminium	7429-90-5	N/A
Polypropylene	N/A	N/A

The unit does not contain any human source material.

SECTION 4 FIRST AID MEASURES

Description of first aid measures:

General advice:Immediate medical attention is required. Show this safety data sheet (SDS) to the doctor in attendance.

Inhalation: Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult give oxygen.

Ingestion: May be harmful if swallowed in large quantity. Induce vomiting immediately as directed by medical personnel.

Skin Contact: Wash off with plenty of water, take off contaminated clothing and shoes immediately.

Eye Contact: Wash with running water or saline, Seek medical attention if necessary.

SECTION 5 FIREFIGHTING MEASURES

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

Unusual Fire and Explosion Hazards: The nitrocellulose membrane is classified as a flammable solid. Keep away from excessive heat, fire or flame.

Special Protective Equipment for Fire-fighter: Wear self-contained breathing apparatus for fire fighting if necessary.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Take proper precautions to minimize exposure by using appropriate personal protective equipment. Shut off all sources of ignition.

Environmental Precautions: Prevent further leakage or spillage if safe to do so. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust) and remove

SECTION 7 HANDLING AND STORAGE

Precautions for handling: Avoid contact between test area and skin, eyes or clothing. Wash thoroughly after handling.

Information about protection against explosions and fires: This product is not flammable

Precautions for storage: Store at 4- 30°C in original sealed package.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

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

General protective and hygienic measures: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Follow the usual biosafety practices for handling potentially infectious

materials.

Engineering Controls: Minimize any anticipated skin and eye contact with test strip.

Eye Protection: Face shield and safety glasses

Respiratory Protection: Inhalation not anticipated in intended use. Respiratory protection not necessary.

Skin Protection: Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact

Hand Protection: Wear protective gloves (such as butyl rubber), passing the tests according to EN 374(EU), USF739 or AS/NZS 2161.1 standard.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

SECTION 9 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: 200° C (nitrocellulose membrane)

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

SECTION 10 STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: No data available.

Incompatible materials: Strong oxides, strong acids, strong bases.

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

Conditions to Avoid: Excessive heat, direct sunlight (nitrocellulose)

SECTION 11 TOXICOLOGICAL INFORMATION

Acute Toxicity: LD/LC50 values that are relevant for classification: no data available

Sensitisation: no data available

Chronic Toxicity (Target Organ Effects): no data available

Reproductive and Developmental Toxicity: no data available

Carcinogenicity: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Potential Health Effects:

Inhalation: no data available

Ingestion: Toxic if swallowed.

Skin: Toxic if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

SECTION 12 ECOLOGICAL INFORMATION

Toxicity: no data available

Bioaccumulative potential: no data available

Mobility in soil: no data available

Persistence and Degradability: no data available

Ecotoxicity effects: no data available

Further Information on Ecology: no data available

Other adverse effects: no data available

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal considerations: Recycle as much as possible. If it cannot be recycled, use incineration for disposal. Do not dispose of this product by means of discharge to the sewer.

Waste chemicals: Contaminated packaging: Residual hazards may still exist after the contents of the packaging are emptied. Keep away from heat and sources of ignition. If possible, recycle them to the supplier for recycling.

SECTION 14 TRANSPORT INFORMATION

Land Transport (ADR/RID): Not dangerous goods.

Air Transport (ICAO/IATA): Not dangerous goods.

Maritime Transport (IMO-IMDG): Not dangerous goods.

SECTION 15 REGULATORY INFORMATION

SARA 302 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302**.**

SARA 313 Components: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

EINECS , TSCA , DSL IECSC , NZioC , PICCS ,KECL , AICS Status: This product does not contain any hazardous ingredients above trigger levels.

EEC Classification and Labeling: None required.

SECTION 16 OTHERS

The above information is believed to be correct but does not purport to be allinclusive 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.

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00157071

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA05**		
	Bezeichnung / Name **Behörde für Justiz und Verbraucherschutz, Referat V43**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20539**
	Straße, Haus-Nr. / Street, house no. **Billstraße 80**		
	Telefon / Phone **+49-40-428280**		Telefax / Fax **+49-40-427310017**
	E-Mail / E-mail **medizinprodukte@justiz.hamburg.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **03.08.2020**		Registriernummer / Registration number **DE/CA05/IvD-238321-1547-00**
	Typ der Anzeige / Notification type S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change £ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG £ Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative £ Einführer / Importer £ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG £ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV £ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000040627**		
	Bezeichnung / Name **Shanghai International Holding Corporation GmbH (Europe)**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestrasse 80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hangzhou Clongene Biotech Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Hangzhou**		Postleitzahl / Postal code **311121**
	Straße, Haus-Nr. / Street, house no. **No.1 Yichuang Road, Yuhang Sub-district, Yuhang District,**		
	Telefon / Phone **+86-571-88262120**		Telefax / Fax **+86-571-88262112**
	E-Mail / E-mail **clongene@clongene.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Liang Jin**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestr.80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	£ Erstanzeige / Initial notification S Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device
Klassifizierung / Classification £ Produkt der Liste A, Anhang II / Device of List A, Annex II £ Produkt der Liste B, Anhang II / Device of List B, Annex II £ Produkt zur Eigenanwendung / Device for self-testing S Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
App (Software auf mobilen Endgeräten) £ ja / yes S nein / no
Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG £ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
Handelsname des Produktes / Trade name of the device **Clongene**
Produktbezeichnung / Name of device **COVID-19 Antigen Rapid Test**
Angabe der benutzten Nomenklatur / Nomenclature used S EDMS-Klassifikation / EDMS Classification £ GMDN
Nomenklaturcode / Nomenclature code **15-70-90-90-00**
Nomenklaturbezeichnung / Nomenclature term **OTHER OTHER VIROLOGY RAPID TESTS**
Kurzbeschreibung / Short description In Deutsch / In German
In Englisch / In English **COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.**

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	£ In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Hamburg**

Datum
Date **2020-07-25**

Name **Liang Jin**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Sylvia Frenzel**		Telefon / Phone **040 42837-2120**