



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
Tel: +86-571-88262120 Web: www.clongene.com
Fax: +86-571-88261752 Email: marketing@clongene.com

Material Safety Data Sheet

SECTION 1 Identification of the Substance and of the Company

Product name: COVID-19/Influenza A+B Antigen Combo Rapid Test

Brand: CLUNGENE

Date: 2 September, 2020

Manufacturer: Hangzhou Clongene Biotech Co., Ltd.

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

Telephone: 0086-571-88262113

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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

List of ingredients

1. Nitrocellulose membrane coated with a control line and a test line

Component	CAS #	% W/V
Nitrocellulose	9004-70-0	≤100%
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%

2. Absorbent Paper

Component	CAS #	% W/V
Cellulose microcrystalline	113669-95-7	≤100%

3. Fiberglass membrane coated with latex

Component	CAS #	% W/V
Fiberglass	65997-17-3	≤100%
Antibody	N/A	<3%

4. Desiccant

Component	CAS #	% W/V
Silica gel	112945-52-5	≤100%

5. Foil pouch and label



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Component	CAS #
Poly(Ethylene Terephthalate)	25038-59-9
Aluminium	7429-90-5
Polypropylene	N/A

6. Buffer

Component	CAS #	% W/V
NaCl	7647-14-5	<1%
Water	7732-18-5	> 95%

7. Chemical characterization - mixtures

Chemical Name	In% By Weight	CASNo.
75% Ethyl Alcohol	75%	64-17-5
RO Purified Water	25%	7732-18-5
Nonwoven Fabric	/	/

The unit does not contain any human source material.

SECTION 4 First Aid Measures

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

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

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

SECTION 5 Firefighting Measures

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

Environmental Precautions: Place in container for disposal according to local/ national regulations for handling of bio-hazardous waste.

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

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

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

SECTION 8 Exposure Controls/Personal Protection



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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.

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

Water Solubility: Nitrocellulose: insoluble

Reagents: soluble

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



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Acute Toxicity: no data available

Irritancy and Corrosion: 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 under current edition of the IATA dangerous goods regulation 61st edition of 2020.

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 Other information



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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.

Number: MSDS 09001

Written by: Liping Fu

Approved: Zhiqiang Yin

Date: 2020.09.02

