



Hangzhou Clongene Biotech Co.,Ltd.

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SAFETY DATA SHEET

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

Version: 2.5

Issue Date: 22 November 2021

Revision Date: 12 August 2022

SECTION 1 IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1. Product identifier

Product name: COVID-19 Antigen Rapid Test

REF ISCOVu002-A001, ISCOVu002-A005, ISCOVu002-A025

REF ISCOVu002-B001, ISCOVu002-B005, ISCOVu002-B007, ISCOVu002-B010, ISCOVu002-B020, ISCOVu002-B025

Brand: **CLUNGENE**

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

1.2.1. Relevant identified uses

Industrial/Professional use spec: For self-testing and in vitro diagnostic use only.

1.2.2. Uses advised against

Restrictions on use: For use as part of an IVD method, only.

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

1.4. Emergency telephone number

Emergency number: 0086-571- 88262120

SECTION 2 HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

The product is a kit consisting of individual ingredients, such as test cassette and extraction reagent. Both of the individual ingredients are not classified as hazardous in accordance with REGULATION (EC) 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/vPvB criteria according to REACH, 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

3.2. Mixture

Extraction Reagent



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

Test Cassette

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.

Inhalation: In case of accident by inhalation: remove exposed individual 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.

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.

SECTION 5 FIREFIGHTING MEASURES

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.

SECTION 6 ACCIDENTAL RELEASE MEASURES

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.

6.4. Reference to other sections

None.

SECTION 7 HANDLING AND STORAGE

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.



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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.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

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: No special measures are necessary. But when unscrewing the lid of extraction reagent, avoid the extraction reagent outlet facing your face.

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

Skin Protection: No special measures are necessary.

Hand Protection: No special measures are necessary.

Environmental exposure controls: No special precautionary measures are necessary.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Extraction Reagent

Appearance: liquid.

Color: colorless.

Odor: odorless.

pH: 7.4.

Oldor threshold: No data available.

Melting Point/Freezing point: No data available.

Initial boiling point and boiling range: No data available.

Flash Point: No data available.

Evaporation rate: No data available.

Flammability (solid, gas): Not applicable.

Upper/lower flammability or explosive limits: Not applicable.

Vapor pressure: No data available.

Vapor density: No data available.

Relative density: No data available.

Solubility(ies):

Water solubility: completely miscible.

Solubility in other solvents: No data available

Partition coefficient: n-octanol/water: No data available.

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

Decomposition temperature (°C): No data available.

Viscosity: No data available.



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Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Test Cassette

Appearance: Flat, white plastic housing containing white, narrow membrane test strip;

Color: White.

Odor: odorless.

Oldorthreshold: No data available.

pH: Not applicable.

Melting Point/Freezing point: No data available.

Initialboiling pointand boiling range: No data available.

Flash Point: Not applicable.

Evaporation rate: Not applicable.

Flammability (solid, gas): Non flammable.

Upper/lower flammability or explosive limits: No data available.

Vapor pressure: Not applicable.

Vapor density: Not applicable.

Relative density: No data available.

Solubility(ies):

Water solubility: insoluble

Solubility in other solvents: No data available

Partition coefficient: n-octanol/water: No data available.

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

Decomposition temperature (°C): No data available.

Viscosity: Not applicable.

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information

No additional information available.

SECTION 10 STABILITY AND REACTIVITY

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. Conditions to Avoid

Excessive heat, direct sunlight.

10.5. Incompatible materials

Strong oxides, strong acids, strong bases.

10.6. Hazardous decomposition products



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

SECTION 11 TOXICOLOGICAL INFORMATION

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.

SECTION 12 ECOLOGICAL INFORMATION

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. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

SECTION 14 TRANSPORT INFORMATION

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.

SECTION 15 REGULATORY INFORMATION

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 > 0.1 % according to REGULATION (EU) No. 1907/2006 Article 59 (REACH).

15.2. Chemical Safety Assessment

No information available.

SECTION 16 OTHER INFORMATION

Version: 2.5

Revision Information: Mainly revised composition/information on ingredients of Section 3.

Full text of other abbreviations:

PBT- Persistent, Bioaccumulative and Toxic substance

vPvB- Very Persistent and Very Bioaccumulative substance

CMR - Carcinogen, Mutagen or Reproductive Toxicant

REACH-Registration, Evaluation, Authorisation and Restriction of Chemicals

SVHC-Substances of Very High Concern

SDS-safety data sheet



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CLP - Classification Labeling Packaging Regulation; Regulation (EC) No 1272/2008

REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

GHS - Globally Harmonized System

IMDG - International Maritime Dangerous Goods

IMO- International Mari-time Organization

RID-Regulations concerning the International Carriage of Dangerous Goods by Rail

ADR-European Agreement concerning the International Carriage of Dangerous Goods by Road

IATA - International Air Transport Association-

ICAO - International Civil Aviation Organization

UN - United Nations

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.