

Document Approval Page

1. Originator – Document Information			
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Document Title	Material Safety Data Sheet for CT-P60 D-2 04 / CT-P60 D-2 06 (Celltrion DiaTrust™ COVID-19 Ag Home Test)		
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2. Approval Signatures		
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Material Safety Data Sheet

MSDS40

Ver. 1.0

Effective Date
Jun. 04, 2021

Title: Material Safety Data Sheet for CT-P60 D-2 04 / CT-P60 D-2 06 (Celltrion DiaTrust™ COVID-19 Ag Home Test)

1. Identification of the product and supplier

Product Name Celltrion DiaTrust™ COVID-19 Ag Home Test

Company information Celltrion, Inc.
20, Academy-ro 51, Yeonsu-gu,
Incheon, 22014
Republic of Korea
Phone +82-32-850-5000
Fax +82-32-850-5050

2. Hazard identification

Potential Health Hazards Classification of the substance or mixture
Regulation(EC)No.1272/2008(CLP): Not classified as hazardous
Directive 67/548/EEC&Directive 1999/45/EC: Not classified as dangerous for supply/use.

Label elements No measures required.

Other hazards None

3. Composition/information on ingredients

Chemical characterization

Description: *In vitro* diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical/biochemical reagents.

- Monoclonal antibody to SARS-CoV-2 Nucleocapsid
- Monoclonal IgG Specific to RBD of SARS-CoV-2 Spike Protein
- Goat anti-mouse IgG

Dangerous components: The product does not contain reportable quantities of dangerous components.

Additional information: The Test Strip is housed in a hinged cardboard card

4. First-aid measures

Description of first aid measure

- After inhalation: Not relevant for this material.
- After skin contact: Wash skin with soap and water.
- After eye contact: Rinse cautiously with water for several minutes.
- After ingestion: Wash out mouth with water. Consult a doctor in case of complaint.

Most important symptoms: None.

Indication of the immediate medical attention and special treatment needed: None.

5. Fire-fighting measures



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Suitable extinguishing agents: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Special hazards caused arising from the substance or mixture: In case of fire, the following can be released: carbon oxides (CO_x), sulphur oxides (SO_x), nitrogen oxides (NO_x).

Advice for fire-fighters: Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Refer to section 8 for protective measures when handling the spillage.

Environmental precautions: No special measures are required.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (paper toweling, sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to section 13. Rinse off area with water.

Reference to other sections: 13

7. Handling and Storage

Information for safe handling: Avoid contact with skin and eyes. Keep out of reach of children. Wash hands before breaks and after work.

Conditions for safe storage, including any incompatibilities: Store in the original container at 2 to 30°C

Specific end use(s): Use as per instructions for use.

8. Exposure controls/personal protection

Control parameters

- Occupational exposure limits: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Exposure controls

- Appropriate engineering controls: Not relevant for this material.
- Personal protection equipment
 - Eye/face protection: safety glasses recommended(EN166)
 - Hand protection: disposable gloves(EN374)
 - Material of gloves: latex/natural rubber, Nitrile rubber
 - Penetration time of glove material: gloves resistance is not critical when the product is handled according to the instructions for use
- Body protection: Not normally required.

Respiratory protection: Not normally required



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9. Physical and chemical properties

Information on basic physical and chemical

- Form: Solid test strip house in a hinged book shape cardboard holder
- Color: White
- Odor: Odorless

Flash point: Not applicable

Self-igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

10. Stability and reactivity

Reactivity: None known.

Chemical stability: The product is stable in accordance with the recommended storage conditions.

Possibility of hazardous reactions: None Known. Hazardous polymerization will not occur.

Conditions to avoid: None.

Incompatible materials: None Known.

Hazardous decomposition product(s): None Known.

11. Toxicological information

Information on toxicological effects

Mixtures

- Acute toxicity: Based upon the available data, the classification criteria are not met.
- Skin contact: No significant harmful effects anticipated.
- Eye contact: No significant harmful effects anticipated.
- Ingestion: No significant harmful effects anticipated.
- Sensitization: No sensitization effects known.

Other information: Not applicable

12. Ecological information

Toxicity: The product does not contain significant quantities of ingredients that are environmentally toxic.

Persistence and degradability: The product is substantially biodegradable.

Bioaccumulative potential: The product has no potential for bioaccumulation.

Mobility in soil: The product is predicted to have high mobility in soil.

Results of PBT and vPvB assessment: Not applicable.

Other adverse effects: Not applicable.

13. Disposal considerations

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Used device should be disposed if as potentially biohazardous material in compliance with applicable federal, state and local waste management regulations. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Packaging: Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in same manner as the product. Non-contaminated packaging material may be recycled. Contact your local service providers for further information.

14. Transport information

UN number: Not applicable

UN proper shipping name: Not applicable

Transport hazard class(es): Not classified as dangerous in the meaning of IATA/ICAO transport regulations

Packing group: Not applicable

Environmental hazards: Not applicable

Special precautions for user: Not applicable

Transport in bulk according to Annex II of Marpol73/78 and the IBC code: Not applicable

15. Regulatory information

Safety, health and environmental regulation/legislation specific for the substance or mixture: In vitro diagnostics medical device directive 98/79/EC. Water hazard class:(Germany):WGK-

Chemical safety assessment: Not applicable

16. Other information

Additional information: -

The information contained in this document is believed to be correct, but does not purport to be all-inclusive and shall only be used as a guide. Celltrion, Inc. shall not be held liable for any damage resulting from handling or correct with the above product.