

MEDICAL DEVICE ESSENTIAL SAFETY (MATERIAL SAFETY DATA SHEET, MSDS)

Section 1- CHEMICAL PRODUCT

MSDS Name: Coretests® COVID-19 IgM/IgG Ab Test

Section 2- COMPOSITION, INFORMATION ON INGREDIENTS

List of ingredients:

1. Nitrocellulose membrane with backing and coated with a control line and two test lines:
Control line: Goat anti-mouse IgG.
Test line: Mouse anti-human IgG and Mouse anti-human IgM
2. Dry non-woven cloth with colloidal-gold mouse IgG and recombinant COVID-19 antigens conjugate.
3. Absorbent Paper.
4. Mylar plat.
5. Desiccant.
6. Foil pouch and label.
7. Plastic cassette.
8. The product does not contain any human source material.
The product contains recombinant COVID-19 antigens, Mouse IgG and Goat anti mouse polyclonal antibodies.

Section 3- HAZARDS IDENTIFICATION

1. **WARNING STATEMENT:** Signs of “For In Vitro Diagnostic And Professional Use Only” on product labeling and inserts.
2. **Potential Routes of Exposure:** No hazardous exposures has been described or anticipated under such conditions of usage in the related product literature.
3. **Eye:** None.
4. **Skin:** None.
5. **Inhalation:** None.
6. **Ingestion:** None.
7. **Chronic Toxicity:** None known.
8. **Reproductive and Developmental Toxicity:** The components of this product are not considered reproductive or developmental toxins.
9. **Carcinogenicity:** None of the components of this product is listed by NTP, IARC, or OSHA as a Carcinogen.

Section 4- FIRE FIGHTING MEASURES

1. **Unusual Fire and Explosion Hazards:** The nitrocellulose membrane is classified as a flammable solid. Keep away from excessive heat, fire or flame.
2. **Hazardous Combustion Products:** Oxides of carbon and nitrogen.
3. **Extinguishing Media:** Water, carbon dioxide, multipurpose dry chemical or halon-fire extinguisher.
4. **Special Fire Fighting Equipment:** Wear full protective clothing and NIOSH/MSHA-approved positive pressure, self-contained breathing apparatus. Thoroughly wash all equipment after use.

Section 5- ACCIDENTAL RELEASE MEASURES

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

Section 6- HANDLING and STORAGE

1. Avoid contact the test area and test region with skin, eyes or clothing.
2. Wash thoroughly after handling.
3. Store in 4- 30°C in original sealed package until usage, avoid direct sunlight.

Section 7- EXPOSURE CONTROLS, PERSONAL PROTECTION

1. **Occupational Exposure Limits:** There are no established exposure limits for this product, nor indicated for any ingredients.
2. **Eye and Face Protection:** Follow standard laboratory procedure; wear safety glasses with side shields or full face shield if eye contact is likely. The choice of protection should be based on the potential for exposure to the eyes and face.
3. **Respiratory Protection:** Inhalation not anticipated in intended use. Respiratory protection is not necessary under such circumstance.
4. **Skin Protection:** Do follow standard laboratory procedure, wear gloves, lab coat, or other protective garment if skin contact is likely. The choice of skin protection should be based on the job activity and potential for exposure to the skin.
5. **Engineering Controls:** Minimize any anticipated skin and eye contact with test strip.
6. **Other:** Follow standard laboratory procedure, wash hands immediately after handling this material (especially before eating, drinking or smoking).

Section 8- PHYSICAL AND CHEMICAL PROPERTIES

1. **Appearance, Color, Odor:** Flat, white plastic housing containing white, narrow membrane test strip; odorless.
2. **PH:** Not applicable.
3. **Boiling Point:** Not applicable.
4. **Melting Point:** Not applicable.
5. **Molecular Weight:** Not available.
6. **Flash Point:** 200°C (nitrocellulose membrane)
Low Limit: Not available.
High Limit: Not available.
7. **Auto flammability:** Not likely under nature condition and environment.
8. **Explosive Properties:** None.
9. **Oxidize Properties:** None.
10. **Vapor Pressure (mmHg & temp.):** Nil
11. **Specific Gravity (H₂O= 1):** Not available.
12. **Solubility:** Water: Nitrocellulose: insoluble.
Reagents: soluble.
Fat: Not available.
13. **Partition Coefficient:** Not available.
14. **Percent Volatile (%):** Nil.
15. **Vapor Density (air= 1):** Nil.
16. **Evaporation (Butyl Acetate= 1):** Nil.

Section 9- STABILITY AND REACTIVITY

1. **Stability:** Stable under normal conditions of use. Hazardous polymerization is not expected to occur. Over many years nitrocellulose will polymerize and become brown. Polymerization reduces the flash point.
2. **Hazardous Decomposition Products:** Oxides of carbon and nitrogen.
3. **Conditions to Avoid:** Excessive heat, direct sunlight (nitrocellulose).
4. **Incompatibility:** Incompatible with strong acids or alkalis.

Section 10- TOXICOLOGICAL INFORMATION

See Section 3 for Additional Information on Health Hazards.

1. **Inhalation:** None.
2. **Skin (Irritancy and Acute Toxicity):** None.
3. **Eye (Irritancy and Acute Toxicity):** None.
4. **Ingestion:** None.
5. **Chronic Toxicity (Target Organ Effects):** None.
6. **Carcinogenicity:** None.
7. **Reproductive and Developmental Toxicity:** None.
8. **Mutagenicity:** None.

Section 11- ECOLOGICAL INFORMATION

1. **Persistence and Degradability:** No data available.
2. **Aquatic Toxicity:** No data available for this product.

Section 12- DISPOSAL CONSIDERATIONS

Dispose of waste materials according to prescribed national and local regulations.

Section 13- TRANSPORT INFORMATION

1. **Land Transport (ADRIRID):** Not regulated.
2. **Air Transport (ICAO/IATA):** Not regulated.
3. **Maritime Transport (IMO-IMDG):** Not regulated.

Section 14- REGULATORY INFORMATION

1. **EINECS Status:** This product does not contain any hazardous ingredients above trigger levels.
2. **EEC Classification and Labeling:** None required.

Section 15- OTHER INFORMATION

1. The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it shall make their own determination of the effects, properties and protections which pertain to their particular conditions.
2. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material.
3. Caution should be used in the handling and use of the material.