

## Safety data sheet

### 1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name:** **COVID-19 IgG/IgM Rapid Test**

· **Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / the preparation:** Laboratory chemicals

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

· GenSure Biotech Inc.,

· **Address:** B1-78, Rizhongtian Science and Technology Park, No.585 Tianshan Street, Shijiazhuang High-tech Zone, Hebei, China.

· **Contact:** 0311-89937995、0311-89937996

· **Informing department:**

· GenSure Biotech Inc.,

Tel.: +86 (311)89937995

· **Emergency telephone number:**

Tel.: +86 (311)89937996

**Production Address:** 3/F, 1# Building of Boyun, No. 9 Fengchan Road, Shijiazhuang Economic- Technological Development Zone, Hebei, China

### 2 Hazards identification

**Classification of the substance or mixture**

Classification according to Regulation 98/79/EG

The product is not classified according to the CLP regulation.

**Information concerning particular hazards for human and environment:**

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Label elements

**Labelling according to EU guidelines:**

Observe the normal safety regulations when handling chemicals

The product is not subject to classification according to the calculation methods of the "General Classification Guideline for Preparations of the EC" as issued in the last version.

The product is not subject to identification regulations under EC Directives and the Ordinance on Hazardous Materials (GefStoffV).

**Special labelling of certain preparations:**

Warning - this preparation contains substances not yet tested completely.

**Other hazards**

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## Safety data sheet

Trade name: **COVID-19 IgG/IgM Rapid**

(Contd. of page 1)

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Protein mixture, lyophilised
- **Dangerous components:** Void

### 4 First aid measures

- **Description of first aid measures**
- **General information** Instantly remove any clothing soiled by the product.
- **After inhalation**  
Take affected persons into the open air and position comfortably  
Seek medical treatment in case of complaints.
- **After skin contact**  
Instantly wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.
- **After eye contact** Rinse opened eye for several minutes under running water. Then consult doctor.
- **After swallowing**  
Rinse the mouth with water immediately  
Seek immediate medical advice.
- **Information for doctor** No particular measures are known - treat according to symptoms.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**  
CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with a full water jet.
- **Special hazards arising from the substance or mixture**  
Formation of poisonous gases during heating or in fires.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained breathing apparatus.
- **Additional information**  
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Ensure adequate ventilation  
Avoid causing dust.  
Use breathing protection against the effects of fumes/dust/aerosol.  
Avoid contact with eyes and skin.
- **Environmental precautions:**  
Do not allow product to reach sewage system or water bodies.  
Do not allow to enter the ground/soil.
- **Methods and material for containment and cleaning up:**  
Collect mechanically.  
Dispose of the material collected according to regulations.  
Avoid causing dust.  
Ensure adequate ventilation.
- **Reference to other sections**  
Clean the accident area carefully.

(Contd. on page 3)

## Safety data sheet

**Trade name:** **COVID-19 IgG/IgM Rapid**

(Contd. of page 2)

See Section 13 for information on disposal.  
See Section 8 for information on personal protection equipment.

### 7 Handling and storage

- **Handling**
- **Precautions for safe handling**
  - Ensure good ventilation/exhaustion at the workplace.
  - Prevent formation of dust.
  - Avoid contact with the eyes and skin.
  - Avoid spilling
  - Keep eye irrigation utensils (bottle) ready for use at place of work.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and containers:**
  - Store only in the original container.
  - Provide floor trough without outlet.
- **Information about storage in one common storage facility:**
  - Store away from foodstuffs.
  - Store away from oxidizing agents.
- **Further information about storage conditions:**
  - Keep container tightly sealed.
  - Store in a cool place.
- **Recommended storage temperature:** 4-30°C
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
  - The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the compilation were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
  - Keep away from foodstuffs, beverages and food.
  - Wash hands during breaks and at the end of the work.
  - Avoid contact with the eyes and skin.
  - Do not inhale dust / smoke / mist.
  - Take off immediately all contaminated clothing
- **Breathing equipment:** If dust is produced.
- **Recommended filter device for short term use:**



Filter P1

- **Protection of hands:**
  - Protective gloves.

(Contd. on page 4)

## Safety data sheet

Trade name: **COVID-19 IgG/IgM Rapid**

(Contd. of page 3)



Only use chemical-protective gloves with CE-labelling of category III.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Not suitable are gloves made of the following materials:**

Leather gloves

Strong gloves

· **Eye protection:**



Tightly sealed safety glasses.

· **Body protection:** Protective work clothing.

### 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Solid.  
lyophilized

**Colour:** Brown

· **Odour:** Odourless

· **Change in condition**

**Melting point/Melting range:** Not determined

**Boiling point/Boiling range:** Not determined

· **Flash point:** Not applicable

· **Self-inflammability:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive.

· **Density** Not determined

· **Solubility in / Miscibility with**

**Water:** mixable

· **Other information** No further relevant information available.

### 10 Stability and reactivity

· **Reactivity**

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

(Contd. on page 5)

## Safety data sheet

Trade name: **COVID-19 IgG/IgM Rapid**

(Contd. of page 4)

- **Possibility of hazardous reactions** none, if used as directed
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** strong oxidizing agents
- **Hazardous decomposition products:** none, if stored and handled correctly.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** irritative effect possible
- **on the eye:** irritative effect possible
- **Sensitization:** Prolonged or repeated exposure may cause allergic reactions in sensitive persons
- **Additional toxicological information:**  
Possibly harmful by inhalation, harmful if swallowed and harmful in contact with skin.  
The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:** Not determined
- **Additional ecological information:**
- **General notes:**  
Water danger class 3 (German Regulation) (Self-assessment): extremely hazardous for water.  
Do not allow product to reach ground water, water bodies or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into soil.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** For disposal, local regulations issued by the authorities must be observed.

- **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 02 00	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 05	chemicals consisting of or containing dangerous substances

- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- **UN-Number**
- **ADR, IMDG, IATA** Void

(Contd. on page 6)

## Safety data sheet

**Trade name: COVID-19 IgG/IgM Rapid**

(Contd. of page 5)

· <i>UN proper shipping name</i>	
· <i>ADR, IMDG, IATA</i>	<i>Void</i>
· <i>Transport hazard class(es)</i>	
· <i>ADR, IMDG, IATA</i>	
· <i>Class</i>	<i>Void</i>
· <i>Packing group</i>	
· <i>ADR, IMDG, IATA</i>	<i>Void</i>
· <i>Special precautions for user</i>	<i>Not applicable.</i>
· <i>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</i>	<i>Not applicable.</i>
· <i>Transport/Additional information:</i>	<i>Not dangerous according to the above specifications.</i>

### 15 Regulatory information

- *Safety, health and environmental regulations/legislation specific for the substance or mixture*
- *National regulations*
- *Water hazard class: Water danger class 3 (Self-assessment): extremely hazardous for water.*
- *Chemical safety assessment: A Chemical Safety Assessment has not been carried out.*

### 16 Other information

*These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*