



Beijing Lepu Medical Technology Co., Ltd.

According to UN GHS (the 8th revised edition)

Material Safety Data Sheet (MSDS)

Product name:	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)
Model No.:	/

Written by: Linda
(Linda)

Inspected by: Jose
(Jose)



Issued by: TUV-Laboratory (China) Service of Testing

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Initial Date: Mar. 20, 2020

Revision Date: Mar. 20, 2020

Material Safety Data Sheet

Product Name: SARS-CoV-2 Antibody Test (colloidal gold immunochromatography) Item No.: 20A010A027
MSDS No.: EMS.200.320.002.LMT Initial Date: Mar. 20, 2020 Revision Date: Mar. 20, 2020 Version: 1.0

Section 1 - Product and Company Identification

1.1. Product identification

Product name: SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)

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

Identified uses: This product is used to qualitatively detect the content of new coronavirus (sars-cov-2) antibody in clinical samples (serum / plasma / whole blood).

Use advised against: Not available

1.3. Details of the manufacturer or applicant

Applicant: Beijing Lepu Medical Technology Co.,Ltd.

Address: Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China

Telephone: +86-15810326252

1.4. Emergency telephone number

Emergency telephone: +86-15620600985

Section 2 - Hazard Description

Hazard class and label elements of the product according to GHS (the 8th revised edition):

2.1. GHS Classification of substance or mixture:

Non-hazardous substance or mixture.

2.2. Label elements:

Hazard pictograms: Not applicable.

Signal word: Not applicable.

Hazard statements: Not applicable.

2.3. Other Hazards: None.

Section 3 - Composition / Ingredient Data

3.1. Material: Not applicable

3.2. Mixture: Applicable

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Chemical name	CAS No.	%(by weight)
ABS (Test strip shell)	9003-56-9	60.0
PVC (Plastic carrier board)	9002-86-2	17.0
Suction plate	N/A	7.0
Nitrocellulose membrane	N/A	1.5
Glass cellulose membrane	N/A	1.5
Chloroauric acid	16903-35-8	1.0
Poly(ethylene glycol) 20000	25322-68-3	0.5
Trehalose	99-20-7	0.5
Sodium phosphate monobasic	7558-80-7	0.5
Sodium phosphate dibasic dodecahydrate	10039-32-4	0.5
Sodium chloride	7647-14-5	0.5
Boric acid	11113-50-1	0.5
Sodium tetraborate	1330-43-4	0.5
Polysorbate 20	9005-64-5	0.5
Sucrose	57-50-1	0.5
Surfactant S7	N/A	0.5
Surfactant S9	N/A	0.5
PVP-40	9003-39-8	0.5
SDS-L	2386-53-0	0.5
MES	145224-94-8	0.5
Optimizer L-30	N/A	0.5
Proclin 300 (P-300)	N/A	0.5
Bovine albumin	9048-46-8	0.5
TRIS	77-86-1	0.5

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Chemical name	CAS No.	%(by weight)
Potassium carbonate	584-08-7	0.5
Newborn-Calf Serum	N/A	0.5
SARS-CoV-2 Recombinant protein	N/A	0.5
Mouse anti humanIgM	N/A	0.5
Mouse anti humanIgG	N/A	0.5
Goat anti mouse IgG antibody	N/A	0.5

Section 4 - First Aid Measures

4.1. General advice:

Show this material safety data sheet to the doctor in attendance. After receiving the first-aid measure required, consult a physician if necessary.

Skin contact:

Unlikely to be harmful in normal use. If skin contact melts, flush cooling with plenty of water. Non medical staff to assist, do not remove the cured products. Consult a physician.

Eyes contact:

If the mucous membrane of the eye or the like is irritated by fumes, steam, fine particles, etc., check for and remove any contact lenses, do not rubbing eyes with hand. Provide a readily-accessible eyewash facility and quick-drench safety shower. Occasionally lifting the upper and lower eyelids. Immediately flush eyes with running water, disappear until the chemical residues so far. Get medical attention if irritation occurs.

Inhalation:

No inhalation hazard in normal use. If worker inhales plenty of steam, power or dust, move exposed person to fresh air. Keep person warm and at rest. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway.

Ingestion:

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If the product is in the form of chip and there is a possibility of swallowing:

If swallowed: If swallowed in a large quantity, consult with the physician, though the product is low in oral toxicity.

4.2. Most important acute and delayed symptoms/effects:

The most important known symptoms and effects are described in section 11.

4.3. Immediate / special treatment:

Continue with first aid measures. Treat symptomatically and supportively. Symptoms may be delayed.

Section 5 – Firefighting Measures

5.1. Extinguishing method and extinguishing agent:

Product is hard to burn, if this product is involved in a fire:

Suitable extinguishing agents: Use dry sand, dry chemical or CO₂ foam extinguishing. Water spray can be used to cool fire exposed containers/materials. Use extinguishing media most appropriate for the surrounding fire.

Unsuitable extinguishing agents: None.

5.2. Special hazards arising from the substance or mixture:

If this product is involved in a fire, the following can be released: Carbon oxides, sodium oxides, boron oxides, etc.

5.3. Fire precautions and measures:

Firefighters must wear self-contained breathing apparatus, wear full body fire suit, fire extinguishing in the upwind. As far as possible will be transferred to empty containers from the scene. Keep the fire water spray container cooling, until the end of fire. If the containers in the fire ground have been color, must be evacuated immediately. Isolated accident scene, prohibit access. Receiving and processing of fire, to prevent environmental pollution.

Section 6 - Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures:

No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt

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material, avoid slipping. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions:

Prevent further leakage or spillage if safe to do so. To prevent leak into the water, the basement and limited space. Prevent entry into the sewage system.

6.3. Collecting, clearing method and disposal material:

Pick up and arrange disposal without creating dust. Collect mechanically. Keep in suitable, closed containers for disposal.

Section 7 - Handling and Storage

7.1. Handling precautions:

Avoid formation of dust and aerosols. Put on appropriate personal protective equipment (see section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Avoid contact eyes. Do not ingest. Avoid breathing dust. Normal measures for preventive fire protection. Observe good housekeeping procedures and hygiene practices. Wash thoroughly after handling. Avoid dust formation. Handling carefully to prevent packaging and product is damaged.

7.2. Information about protection against explosions and fires:

Non-flammable and non-explosive. Compliance with fire regulations. Keep away from high temperatures and open flames.

7.3. Conditions for safe storage, including any incompatibilities:

Store in accordance with local regulations. Stored in a dry, cool and well-ventilated area. Keep away from high temperature and open fire, away from incompatible materials (see section 10). Moisture-proof and water-proof. Keep out of reach children.

7.4. Packaging materials:

Recommended-Use original container.

Section 8 - Exposure Controls/ Personal Protection

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8.1. Exposure limit:

Chemical name	CAS No.	Limit
Sodium tetraborate	1330-43-4	ACGIH TLV-TWA 1 mg/m ³
Sucrose	57-50-1	ACGIH TLV-TWA 10 mg/m ³ OSHA PEL (Gen Indu): 8H TWA 5 mg/m ³ , respirable dust

8.2. Engineering control:

There is usually no need to take measures. But if dust, fume, steam arise and the concentration can not be brought to lower than the above-mentioned maximum permissible concentration, such measures as installing local ventilators are taken.

8.3. Personal protection:

Respiratory protection:

Where protection from nuisance le (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Eye protection:

Wear safety glasses when there is a potential for eye contact.

Skin and body protection:

Wear suitable protective clothing.

Hands protection:

Protective gloves.

Other protection:

Smoking, eating and drinking water is forbidden in the workplace. After work, shower and change clothes.

Section 9 - Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

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Appearance:	Rectangular solid
Colour:	White
Odor:	Odorless
Melting point / freezing point(°C):	No data available/Not applicable
Boiling point(°C):	No data available/Not applicable
Flash point(Closed cup, °C):	No data available/Not applicable
Steam pressure(20°C):	No data available/Not applicable
Relative density (water=1, 20°C):	No data available/Not applicable
Partition coefficient: n-octanol/water:	No data available/Not applicable
Decomposition temperature(°C):	No data available/Not applicable
pH value:	No data available/Not applicable
Explosion limit:	Non-explosive
Vapor density:	No data available/Not applicable
Water soluble:	Insoluble in water
Flammability (solid, gas):	Non flammable
Oxidizing properties:	The substance or mixture is not classified as oxidizing

9.2. Other safety information

No data available/Not applicable

Section 10 - Stability and Reactivity

10.1. Stability:

The product is chemically stable.

10.2. Reactivity:

Stable under recommended storage and handling conditions.

10.3. Incompatible materials:

Strong oxidizing agents.

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10.4. Conditions to avoid:

Incompatible materials, water, direct sunlight, high temperature and open fire.

10.5. Hazardous polymerization:

Will not occurs.

10.6. Hazardous decomposition products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11 - Toxicological Information

11.1. Acute toxicity:

Component	CAS No.	LD ₅₀ (Oral)	LD ₅₀ (Dermal)	LC ₅₀ (Inhalation)
Poly(ethylene glycol) 20000	25322-68-3	Rate: 44200mg/kg Rabbit: 28900mg/kg	No data	No data
Sodium phosphate monobasic	7558-80-7	Rate: 8290mg/kg	No data	No data
Sodium chloride	7647-14-5	Rate: 3000mg/kg Mouse: 4000mg/kg	Rabbit: >10000mg/kg	Rate: >42000mg/m ³ /1H
Polysorbate 20	9005-64-5	Rate: >33000mg/kg	No data	No data
Sucrose	57-50-1	Rate: 29700mg/kg	No data	No data
PVP-40	9003-39-8	Rate: 3000mg/kg	No data	No data
TRIS	77-86-1	Rate: 5900mg/kg	No data	No data
Potassium carbonate	584-08-7	Rate: 1870mg/kg Mouse: 2750mg/kg	No data	No data

11.2. Skin corrosion/irritation:

Ingredient name	CAS No.	Species	Route	Value	Result	Type of test
Poly(ethylene glycol) 20000	25322-68-3	Rabbit	Skin	500mg/24H	Mild	Standard Draize test
Sodium chloride	7647-14-5	Rabbit	Skin	500mg/24H	Mild	Standard Draize test

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11.3. Eye corrosion/irritation:

Ingredient name	CAS No.	Species	Route	Value	Result	Type of test
Poly(ethylene glycol) 20000	25322-68-3	Rabbit	Eye	500mg/24H	Mild	Standard Draize test
Sodium chloride	7647-14-5	Rabbit	Eye	100mg/24H	Moderate	Standard Draize test

11.4. Respiratory or skin sensitization:

These products are not known to cause human skin or respiratory sensitization.

11.5. Germ cell mutagenicity:

According to the existing data, the product is not classified.

11.6. Carcinogenicity:

No classification data on carcinogenic properties of this material is available from the EPA, IARC, NTP, OSHA or ACGIH.

11.7. Reproductive toxicity:

According to the existing data, the product is not classified.

11.8. Specific target organ toxicity - single exposure:

According to the existing data, the product is not classified.

11.9. Specific target organ toxicity - repeated exposure:

According to the existing data, the product is not classified.

11.10. Aspiration hazard:

According to the existing data, the product is not classified.

Section 12 - Ecological Information

12.1. Ecotoxicity values:

This product contains no hazardous or toxic substances, and presents a negligible impact on the environment based on its reported use pattern.

12.2. Persistence and degradability:

No data.

12.3. Bioaccumulative potential:

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The potential for bioaccumulation of this material in aquatic organisms is low.

12.4. Mobility in soil:

No data.

12.5. Other adverse effects:

Under environmental conditions, is not expected to have a detrimental effect on plants, animals or microorganisms, but do not allow material to be released to the environment without proper governmental permits.

Section 13 - Disposal Considerations

13.1. Residual waste:

The generation of waste should be avoided or minimized wherever possible. Recycle as much as possible, transfer to a suitable container and arrange for collection by specialized disposal company if recycling is not feasible.

13.2. Contaminated packaging:

The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

13.3. Disposal considerations:

Processing, use or contamination of this product may change the waste management options. Dispose of container and unused contents in accordance with national and local relevant regulations laws.

Section 14 - Transport Information

According to IATA DGR 61th Edition for transportation, IMO International Maritime Dangerous Goods Code (Amendment 39-18), European Agreement Concerning the International Carriage of Dangerous Goods by Road. The products are not subject to ADR, RID, AND, IMDG and IATA DGR.

14.1. UN number

ADR, RID, AND, IMDG, IATA: Not regulated

14.2. UN proper shipping name

ADR, RID, AND, IMDG, IATA: Not regulated

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14.3. Transport hazard class(es)

ADR, RID, AND, IMDG, IATA: Not regulated

14.4. Packing group

ADR, RID, AND, IMDG, IATA: Not regulated

14.5. Environmental hazards

IMDG Marine pollutant: No

14.6. Special precautions for user:

Should check whether the container is full, sealed before shipping. Ensure that the product does not collapse, fall, and not damaged in transport process. Transportation should prevent insolation and high temperature and water. Avoid rain, polluted, damaged, long-term exposure. Stopover should be far away from fire, heat source and high temperature and water.

Section 15 - Regulatory Information

15.1. Regulatory information: Reference to the local, national, US, EU, CA and international regulations.

CAS No.	TSCA	EINECS	DSL	IECSC	NZIoC	PICCS	KECI	AICS
9003-56-9	√	√	√	√	√	√	√	√
9002-86-2	√	√	√	√	√	√	√	√
16903-35-8	√	√	√	√	√	√	√	√
25322-68-3	√	√	√	√	√	√	√	√
99-20-7	√	√	√	√	√	×	√	√
7558-80-7	√	√	√	√	√	√	√	√
10039-32-4	×	√	×	√	√	√	×	√
7647-14-5	√	√	√	√	√	√	√	√
11113-50-1	√	√	√	√	√	√	√	√
1330-43-4	√	√	√	√	√	√	√	√
9005-64-5	√	√	√	√	√	√	√	√
57-50-1	√	√	√	√	√	√	√	√

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CAS No.	TSCA	EINECS	DSL	IECSC	NZIoC	PICCS	KECI	AICS
9003-39-8	√	√	√	√	√	√	√	√
2386-53-0	√	√	×	√	√	√	√	√
145224-94-8	×	√	×	×	√	×	×	×
9048-46-8	√	√	√	√	√	√	√	√
77-86-1	√	√	√	√	√	√	√	√
584-08-7	√	√	√	√	√	√	√	√

TSCA: United States Toxic Substances Control Act Inventory

EINECS: European Inventory of Existing Commercial Chemical Substances

DSL: Canadian Domestic Substances List

IECSC: China Inventory of Existing Chemical Substances

PICCS: Philippines Inventory of Chemicals and Chemical Substances

NZIoC: New Zealand Inventory of Chemicals

KECI: Existing and Evaluated Chemical Substances

AICS: List of existing chemical substances in Australia

Note

“√” Indicates that the substance included in the regulations

“×” That no data or included in the regulations

Section 16 - Other Information

Abbreviations or phrases:

ACGIH	: American Conference of Governmental Industrial Hygienists
ADR	: European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	: Chemical Abstracts Service
CLP	: Classification, labeling and packaging
EC	: Council of Europe

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ECHA	: European Chemicals Agency
EINECS	: European Inventory of Existing commercial Chemical Substances
GHS	: Globally Harmonized System of Classification and Labelling of Chemicals
IARC	: International Agency for Research on Cancer
IATA	: International Air Transport Association
ICAO	: International Civil Aviation Organization
IMDG	: International Maritime Dangerous Goods Code
IC50	: Inhibitory Concn Triton 50%
LC50	: Lethal Concentration 50%
LD50	: Median Lethal Dose 50%
MAPROL	: International Convention for the Prevention of Pollution from Ships
REACH	: REGULATION concerning the Registration, Evaluation, Authorization and Restriction of Chemicals
RID	: Regulation for rail International transportation of Dangerous goods
STEL	: Short Term Exposure Limit
TWA	: Time Weighted Average
MAC	: Maximum Allowable Concentration
OSHA	: Occupational Safety and Health Administration
NIOSH	: National Institute for Occupational Safety and Health
TLV	: Threshold Limit Value
TLV-TWA	: Threshold Limit Value-Time Weighted Average
TLV- STEL	: Threshold Limit Value-Short term Exposure Limit
PC-TWA	: Permissible Concentration-Time Weighted Average
PC-STEL	: Permissible Concentration-Short Term Exposure Limit
PEL	: Permissible Exposure Limit
OELs	: Occupational Exposure Limits

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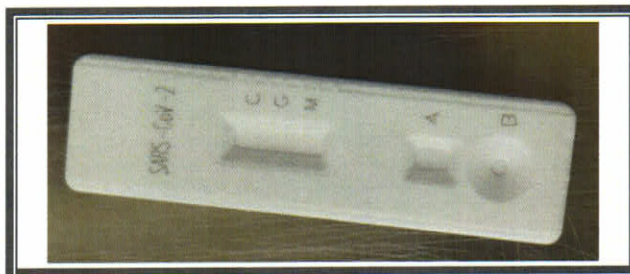
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