


MATERIAL SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**
- Trade name: One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)
Model name: CG20615
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
- Identified use(s): In vitro diagnostic reagent. For self-test.
- 1.3 Details of the supplier of the safety data sheet**
- Company Identification: Getein Biotech, Inc.
No.9 Bofu Road, Luhe District, Nanjing, 211505 China
- Telephone: +86 25 68568508
Fax: +86 25 68568500
E-Mail: tech@getein.com.cn overseas@getein.com.cn
- 1.4 Emergency telephone number**: +86 25 68569089

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 NEPA ratings (scale 0-4)**
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- Health =1; Fire = 0; Reactivity = 0
- 2.2 Classification of the substance or mixture**
- Classification according to GHS: Not classified as dangerous goods
Classification according to Regulation (EC) No 1272/2008: The product is not classified according to the CLP regulation.
Classification according to OSHA Hazard Communication Standard (29 CFR 1910.1200):
The product is not classified according to OSHA Hazard Communication Standard (29 CFR 1910.1200)
Labeling according to GHS and GLP: Not applicable
Hazard pictograms: Not applicable
Signal word: Not applicable
Hazard statements: This mixture is considered as non dangerous mixture.
Precautionary statements: Not applicable
Other hazards: See section 11
Results of PBT and vPvB assessment: Not applicable
Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: This material is not a carcinogen. Classified NONE by NTP, OSHA and by IARC.
MUTAGENIC EFFECTS: Not available. Not applicable
TERATOGENIC EFFECTS: Not available. Not applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Description: In vitro diagnostic reagent test device.
Laminated test strip consisting of solid support materials impregnated with immunochromatography reagents and antibody
Sample extraction solution composed of Phosphate buffered saline (20mM), Na₃N(0.1%), CTAB (0.15%, w/v), NaCl (2%, w/v), and Tween20 (1.0%); pH 7.2±0.5.

Dangerous components: None

3.2 Additional Information

See section 16.

SECTION 4: FIRST AID MEASURES



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4.1	Description of first aid measures	Store in original container at 4 to 30°C.
	General information	The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.
	Inhalation	Supply fresh air; consult doctor in case of complaint.
	Skin Contact	Wash skin with soap and water.
	Eye Contact	Rinse cautiously with water for several minutes. Consult doctor in case of complaint.
	Ingestion	Wash out mouth with water. Consult a doctor.
4.2	Most important symptoms and effects, both acute and delayed	None.
4.3	Indication of the immediate medical attention and special treatment needed	None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1	Extinguishing media Suitable Extinguishing Media	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
5.2	Special hazards arising from the substance or mixture	In case of fire, the following can be released: Hazardous fumes and vapours.
5.3	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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1	Personal precautions, protective equipment and emergency procedures	Refer to Section 8 for protective measures when handling the spillage.
6.2	Environmental precautions	Avoid release to the environment.
6.3	Methods and material for containment and cleaning up	Collect material and dispose of as waste according to Section 13
6.4	Reference to other sections	8, 13

SECTION 7: HANDLING AND STORAGE

7.1	Precautions for safe handling	Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children. Specimens should be handled as potentially infectious materials. Refer to Directive 2000/54/EC for information on handling biohazardous materials. Wash hands before breaks and after work. Clean work areas with hypochlorite or other disinfecting agent.
7.2	Specific end use(s)	Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Ventilation and Engineering controls: No special ventilation and engineering controls are required.

Respiratory Protection: No special respiratory protection is required for use of these products. If respiratory protection is needed, use only protection applicable U.S. State or EU regulations.

Body Protection: General protective clothing.

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Eye Protection:



Hand protection Disposable gloves. (EN374).

Protective Gloves:



Eye/face protection Safety glasses recommended. (EN166)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents. White.

Colour

No odour.

Odour

Not applicable

Odour Threshold (ppm)

Not determined

pH (Value)

Not determined

Melting Point (°C) / Freezing Point (°C) Not deter

Boiling point/boiling range (°C): Not determined

Flash Point (°C) Not applicable

Evaporation rate (BA = 1)

Not applicable

Flammability (solid, gas)

Not determined

Explosive limit ranges

Not applicable

Vapour Pressure (mm Hg)

Not applicable

Vapour Density (Air=1)

Not applicable

Density (g/ml)

Not determined

Solubility (Water)

Not determined

Solubility (Other)

Not determined

Partition Coefficient (n-Octanol/water)

Not determined

Auto Ignition Temperature (°C) Not determined

Decomposition Temperature (°C) Not determined

Viscosity (mPa.s)

Not determined

Explosive properties

Not explosive.

Oxidising properties

Not oxidising

9.2 Other information

Not available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None known.

10.2 Chemical stability

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

storage conditions.

10.3 Possibility of hazardous reactions

None known. Hazardous polymerisation will not occur.

10.4 Conditions to avoid

None

10.5 Incompatible materials

None known..

10.6 Hazardous Decomposition Product(s)

None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	No data
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	No data
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated
Eye Contact	No significant harmful effects anticipated
Ingestion	No significant harmful effects anticipated

11.2 Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The product is likely to persist in the environment.
12.3 Bioaccumulative potential	None anticipated.
12.4 Mobility in soil	The product is predicted to have low mobility in soil.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other adverse effects	Not applicable

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product:	Used devices should be disposed of as potentially biohazardous material in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
European waste catalogue:	18 01 03.
Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

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SECTION 14: TRANSPORT INFORMATION

UN Proper Shipping Name: Not applicable.
UN Number: Not applicable.
Packing Group: Not applicable.
Marine Pollutant: Not available.
Hazardous Substance Reportable Quantity: Not available.
Special Provisions for Transport: Not applicable.
DOT Classification for Bulk Shipments: Not a DOT controlled material (United States).
TDG Classification: Not controlled under TDG.
ADR/RID Classification: Not controlled under ADR (Europe)
IMO/IMDG Classification: Not Controlled under IMDG.
ICAO/IATA Classification: Not controlled under IATA.

SECTION 15: REGULATORY INFORMATION

TSCA inventory: Most components are listed as commercial status active on the TSCA.

SARA 301/302/303: No chemicals in this product are listed as extremely hazards substances in 40 CFR 355, Emergency Planning and Notification (Appendix A to Part 355).

WHMIS: Not controlled under WHMIS.

California Prop.65: There are no Proposition 65 chemicals present in this products levels that would require a warning under the California Safe Drinking Water and Toxic Enforcement Act.

REACH Regulation List of Substances of very high concern (SVHC): None of the ingredients is listed.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out

SECTION 16: OTHER INFORMATION

The contents and format of this MSDS are in accordance with ISO Commission Directive ISO11014:2009.

DISCLAIMER OF LIABILITY

The information in this MSDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This MSDS was prepared and is to be used only for this product. If the product is used as a component in another product, this MSDS information may not be applicable.

Abbreviations and acronyms:

NFPA: National Fluid Power Association.
GHS: Globally Harmonized System of Classification and Labelling of Chemicals.
CLP: Classification, labeling and packaging.
NTP: National Toxicology Program.
OSHA: Occupational safety and health administration.
IARC: International Agency for Research on Cancer.
PBT: Persistent, Bioaccumulative and Toxic.
vPvB: very Persistent and very Bioaccumulative.

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- CAS: Chemical Abstracts Service (division of the American Chemical Society).
- LC50: Lethal concentration, 50 percent.
- LD50: Lethal dose, 50 percent.
- DOT: U.S. Department of Transportation.
- TDG: Transportation of Dangerous Goods Program.
- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road).
- RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail).
- IMO: International Maritime Organization.
- IMDG: International Maritime Code for Dangerous Goods.
- IATA: International Air Transport Association.
- ICAO: International Civil Aviation Organization.
- TSCA: Toxic Substances Control Act.
- WHMIS: Workplace Hazardous Materials Information System

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that e