

Safety Data Sheet

according to 1907/2006/EC, Article 31

Printing date 06.15.2021

Revision: 06.15.2021

1 Identification of the substance/preparation and of the company/undertaking

Product details

· *Product name:* Coronavirus (2019-nCoV)-Antigentest-
Manufacturer: Beijing Hotgen Biotech Co., Ltd
Address: 9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District, Beijing 102600, China
For further information contact: Tel: +86-10-565288
 Fax: +86-10-56528861
 Email: hotgen@hotmail.com.cn

2 Hazards identification

Hazard description:

particular hazards for human and environment:

H302 Harmful if swallowed
 H314 Causes severe skin burns and eye damage.
 H317 May cause an allergic skin reaction.
 H410 Very toxic to aquatic life with long lasting effects.

Classification system:

Cute toxicity, Oral (Category 4), H302
 Skin corrosion (Category 1B), H314
 Skin sensitisation (Category 1), H317
 Acute aquatic toxicity (Category 1), H400
 Chronic aquatic toxicity (Category 1), H410

Precautionary statement(s) Prevention:

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
 P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
 P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

3 Composition/information on ingredients

Chemical characterization

· *Description:* Mixture of substances listed below with nonhazardous additions.

· *Component, Chemical name and Content:*

1) Test cassettes

- a. Colloidal gold (CG) nanoparticles conjugated 2019-nCoV antibody
b. T line

Substance	CAS No.	<u>EC</u> %Present	Symbol(s)	R-Phrases
KV300 (as Preservative) Tris, BSA, mannitol. (2)	26628-22-8	0.05	[T+, N]	R:28-32-50/53

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2) Sample extraction buffer

Substance	CAS No.	<u>EC</u> %Present	Symbol(s)	R-Phrases
NaCl	7647-14-5	1.76		
Na ₂ HPO ₄ · 12H ₂ O	7558-79-4	0.714		
KH ₂ PO ₄	7778-77-0	0.136		
Tween -20	9005-64-5	0.5		
KV300 (as Preservative)	26628-22-8	0.1	[T+, N]	R:28-32-50/53

Aqueous solution containing phosphate buffer and so on. (pH: 7.2)

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4 First aid measures

- **General information:** In case of overexposure, medical observation for at least 48 hours after the incident is recommended.
- **After inhalation:** Of mists or aerosol: Remove to fresh air and contact a doctor.
Of vapors: Remove to fresh air. If symptoms develop seek medical attention.
Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical treatment.

5 Fire-fighting measures

- **Flammable properties:** Nonflammable
- **Extinguishing media:** Use suitable extinguishing media for the fire conditions. (water, foam, dry chemical, carbon dioxide etc.)
- **Fire fighting instructions:** Wear suitable extinguishing apparatus for the fire conditions.
Do not contact to the components when extinguish fire.
- **Measures for environmental protection:** Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **Measures for cleaning/collecting:** Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **Special hazards arising from the substance or mixture:** Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas.

7 Handling and storage

- **Handling:**
- **Information for safe handling:** Keep away from heat and direct sunlight.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols. Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in unopened original receptacles.
Avoid storage above 100 °F, exposure to light, loss of dissolved air, loss of inhibitor, and contamination with incompatible materials.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
Protect from exposure to the light.
Avoid loss of dissolved air, loss of inhibitor, and contamination with incompatible materials.
- **Maximum storage temperature:** < 38 °C (100 °F)

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients 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 valid during the making were used as basis.

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Personal protective equipment:

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.
 Immediately remove all soiled and contaminated clothing
 Wash hands before breaks and at the end of work.
 Avoid contact with the eyes and skin.
 Handle with gloves. Gloves must be inspected prior to use.
 Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Control of environmental exposure:

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided. Wash hands before breaks and at the end of work.

9 Physical and chemical properties

General Information

<i>Form:</i>	Fluid
<i>Colour:</i>	According to product specification
<i>Odour:</i>	Characteristic

Change in condition

<i>Melting point/freezingpoint:</i>	No data available
<i>Boiling point/Boiling range:</i>	No data available

Flash point: No data available

Self-igniting: Product is not self-igniting.

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

Density: No data available

Solubility in / Miscibility with Sample extration buffer: Not miscible or difficult to mix.

10 Stability and reactivity

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

Materials to be avoided: Oxidizers, amines, strong Lewis acids, mineral acids, and thiosulfates

Dangerous reactions No dangerous reactions known.

Dangerous decomposition products:
 Irritant gases/vapours
 Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas
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Incompatible materials: Strong oxidizing agents, Reducing agents, Amines, Mercaptans.

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11 Toxicological information

- Acute toxicity:** LD50 Oral - Rat - 862 mg/kg
LD50 Dermal - Rabbit - 2,800 mg/kg
- Skin corrosion/irritation:** Skin - Rabbit
Result: Corrosive
- Serious eye damage/eye irritation:** Eyes - Rabbit
Result: Corrosive to eyes
- Respiratory or skin sensitisation:** Guinea pig
Result: May cause sensitisation by skin contact.
- Carcinogenicity:** IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- Additional Information:** No RTECS: Not available

Burning sensation, cough, wheezing, laryngitis, shortness of breath, spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonitis, pulmonary edema, Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin., to the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12 Ecological information

- Ecotoxicological effects:**
- Acquatic toxicity:*
- General notes:** Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Harmful to aquatic organisms

13 Disposal considerations

- Product:**
- Recommendation* Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Offer surplus and non-recyclable solutions to a licensed disposal company.
- Uncleaned packaging:**
- Recommendation:* Disposal must be made according to official regulations.

14 Transport information

Land transport ADR/RID (cross-border)

ADR/RID class: -

Maritime transport IMDG:

IMDG Class: -

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA Class:

15 Regulatory information

- National regulations:**
- Class Share in %* 0