Material Safety Data Sheet

according to Regulation (EC) No 1907/2006

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

＜Product Name＞

Coronavirus (2019-nCoV)-Antigentest

<Details of the supplier of the safety data sheet

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＜General Use＞
Reagent for in vitro diagnostics use

＜Product Description＞
Coronavirus (2019-nCoV)-Antigentest packaging five components below.

1) Test cassettes (containing below)
Colloidal gold (CG) nanoparticles conjugated 2019-nCoV antibody
T line; containing 2019-nCoV antibody
C line; containing sheep anti-mouse.

2) Sample extraction buffer

3) Disposable virus sampling swab

4）Biosafety bag

5）Instructions for use

2. COMPOSITION, INFORMATION ON INGREDIENTS

＜Component, Chemical name and Content＞

1) Test cassettes

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

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

c. C line

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

2) Sample extraction buffer

Substance	CAS No.	%Present	EC Symbol(s)	R-Phrases
Sodium azide(as Preservative)	26628-22-8	0.05	[T+, N]	R:28-32-50/53

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

Chemical characterization

The product does not contain dangerous substances according to REGULATION (EU) No. 2015/830, Annex II, Part A , 3.2.2. that must be mentioned in Chapter 3.

Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

3. HAZARDS IDENTIFICATION

3.1 **Classification of the substance or mixture**

Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

3.2 **Label elements**

Additional advice on labelling

Labelling according to Regulation (EC) No. 1272/2008 [CLP]: none

3.3 **Other hazards**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

No risks worthy of mention. Please observe the information on the safety data sheet at all times.

4. FIRST AID MEASURES

4.1 General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

《Inharation》

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

《After contact with skin 》

Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.

《After contact with eyes 》

Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.

《After ingestion》

Rinse mouththoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

4.2 Most important symptoms and effect ,both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Flammable properties

Nonflammable

5.2 Extinguishing media

Use suitable extinguishing media for the fire conditions. (water, foam, dry chemical etc.)

5.3 Fire fighting instructions

Wear suitable extinguishing apparatus for the fire conditions.

Do not contact to the components when extinguish fire.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Safe handling: see section 7

Personal protection equipment: see section 8

Discharge into the environment must be avoided.

6.2. Environmental precautions

Take up mechanically.

Treat the recovered material as prescribed in the section on waste disposal .

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.3. Methods and material for containment and cleaning up

Disposal: see section 13

7. HANDLING AND STORAGE

7.1 Handling

Seal the cap exactly.

Use suitable equipments.

Do not mouth pipette.

Do not leak, overflow and scatter.

Do not fall down and damage.

7.2 Storage

Store in dry place at 39-86°F (4-30℃).

8． EXPOSURE CONTOROLS, PERSONAL PROTECTION

8.1. Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Appropriate engineering controls

No special measures are necessary.

Protective and hygiene measures

Always close containers tightly after the removal of product. When using do not eat, drink, smoke, sniff. Wash Hands before breaks and after work.

Eye/face protection

No special measures are necessary.

Hand protection

Suitable gloves type: Single-use gloves.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Before using check leak tightness / impermeability. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Environmental exposure controls

No special precautionary measures are necessary.

9． PHYSICAL AND CHEMICAL PROPERTIES

＜Appearance＞

1) Test cassettes	
a. Colloidal gold (CG) nanoparticles conjugated 2019-nCoV antibody	Lyophilized solid
b. T line	Lyophilized solid
c. C line	Lyophilized solid
2) Sample extraction buffer	Liquid

＜Color and Odor＞

1) Test cassettes	
a. Colloidal gold (CG) nanoparticles conjugated 2019-nCoV antibody	White，Odorless
b. T line	White-Slightly yellow, Slightly sulfurous odor
c. C line	White-Slightly yellow, Slightly sulfurous odor
2) Sample extraction buffer	Clear, Odorless

＜pH＞

1) Test cassettes	
a. Colloidal gold (CG) nanoparticles conjugated 2019-nCoV antibody	—
b. T line	—
c. C line	—
2) Sample extraction buffer	7.2

＜Vapor pressure＞

No information available.

＜Vapor density＞
No information available.
＜Boiling point＞
No information available.
＜Freezing/melting point＞
No information available.
<Flash point>
No information available

＜Solubility in water＞

1) Test cassettes	
a. Colloidal gold (CG) nanoparticles conjugated 2019-nCoV antibody	Mix free to water.
b. T line	Mix free to water.
c. C line	Mix free to water.
2) Sample extraction buffer	Mix free to water.

＜Specific gravity or densit＞
No information available.
＜Vapor pressure＞
No information available.
＜Boiling point＞
No information available.
＜Freezing/melting point＞
No information available.
＜Flash Point＞
No information available

10. STABILITY AND REACTIVITY

＜Chemical stability＞
Product is stable under normal handling and storage conditions.
＜Conditions to avoid＞
Do not freeze.
＜Incompatibility with other materials＞
No information available.
＜Hazardous decomposition products＞
No information available.
＜Hazardous polymerization＞
No information available.

11. TOXICOLOGICAL INFORMATION

＜Acute inhalation effect＞
No information available.
＜Eye effect＞
May cause eye irritation.
＜Skin effect＞
Ingestion may cause nausea, vomiting, stomach-ache and diarrhea.
＜Acute oral effect＞
Ingestion may cause nausea, vomiting, stomach-ache and diarrhea.
＜Subchronic effect＞
No information available.
＜Chronic effect/Carcinogenicity＞
No information available.
＜Mutagenicity＞
No information available.

Notes about Sodium azide for information.
Sodium azide
Cause inflammation and irritation of eyes, nose, throat and bronchus.
Inhalation and ingestion cause headache, vomiting, dizziness, low blood pressure, difficulty breathing, sense disorder. In serious case, fatality may occur from acute cardiac collapse, and unconsciousness, systemic convulsion. The symptomsmay be delayed.

p.o.	Human	LD0	710μg/kg	(3)
p.o.	Rat	LD50	27mg/kg	(3)
i.p.	Mouse	LD50	28mg/kg	(3)
par	Rabbit	LD50	20mg/kg	(3)

12. ECOLOGICAL INFORMATION

＜Ecotoxicity＞
No information available.
＜Environmental fate＞
No information available.

＜Physical/Chemical Properties＞
No information available.

13. DISPOSAL CONSIDERATIONS

Comply with all EU, national (U.S.federal, state) and local regulations.

Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal. Non-contaminated packages may be recycled.

According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.

Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products / used product

200132 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); medicines other than those mentioned in 20 01 31

List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

Handle contaminated packages in the same way as the substance itself.

14. TRANSPORT INFORMATION

Proper shipping name : In vitro diagnostic reagents

Hazard Class: None

Identification Number: None

The substance is not subject to IATA DGR (61st Edition 2020). Non dangerous according to IATA DGR (61st Edition 2020). The substance can be shipped by air.

Transport in bulk according to Annex II of Marpol and the IBC Code

15. REGULATORY INFORMATION

Follow all the regulations in your country

Please refer to national measures that may be relevant.

Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

2010/75/EU (VOC): no information available

2004/42/EC (VOC): no information available

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2019/957) The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

in vitro diagnosis. - 2017/746/EC

REACH 1907/2006 Appendix XVII, No (mixture): not relevant

National regulatory information

Water hazard class (D): 1 - slightly

16. OTHER INFORMATION

＜reference＞

(1)RTECS (Registry of Toxic Effects of Chemical Substances. NIOSH)

(2)Bovine serum albumin Material Safety Data Sheet from supplier, NOF Corp.(BeiJing YuanHeng ShengMa Biology Technology Resecarch Institute)

(3)Dangerous Properties of Industrial Materials (7th Edition)

(4) CLP: Classification, Labelling and Packaging of substances and mixtures

VOC: Volatile Organic Compounds

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

PBT: Persistent bioaccumulative toxic

vPvB: Very persistent and very bioaccumulative substance

REACH: Registration, Evaluation, Authorisation of Chemicals

TRGS: Technische Regeln für Gefahrstoffe

LD50: Lethal dose, 50 percent

＜Others＞

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