

Material Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier: CorDx™ COVID-19 Ag Test

Model	2 tests/box	5 tests/box	10 tests/box
REF	CO291-02	CO291-05	CO291-10

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

Identified Use:

For use under emergency use authorization (EUA) only

For in vitro diagnostic use only

For use with anterior nasal swab specimens

1.3. Details of the supplier of the safety data sheet

Manufacturer	CorDx, Inc.
Address	9540Waples St Unit C, San Diego, CA 92121
Manufacturing sites	CorDx, Inc. 8940 Kenamar Dr, San Diego, CA 92121, 3719 North Peachtree Rd., Suite 200, Chamblee, GA 30341 Core Technology Co., Ltd. No 30, Area 9, Douda Avenue, Fangshan District, Beijing 102433, P.R. China
Web	CorDx.com
E-mail	info@CorDx.com

SECTION 2: Hazards identification

2.1 Hazard Class (GHS):

Classification according to Regulation (EC) No 1272/2008 (CLP)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

2.2 Label element:

Labelling according to Regulation FDA 21CFR801 not required

Signal word not required

2.3 other hazards:

There is no additional information.

SECTION 3: Composition/information on ingredients

3.1 substance not applicable

3.2 Mixture

This mixture does not meet the criteria for classification.

The unit does not contain any human source material.

3.3 Additional Information. None

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: Immediate medical attention is required. Show this safety data sheet (MSDS) to the doctor in attendance.

Following eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call consult a physician if feeling uncomfortable.

Following skin contact: Such as contact with the skin, rinse with water. Immediately call consult a physician if feeling uncomfortable.

Following inhalation: Move victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Seek medical attention immediately.

Following ingestion:

If it is ingested, rinse the mouth with water.

Do not induce vomiting. Never give anything by mouth to an unconscious person. If you feel uncomfortable, seek medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed Symptoms and effects are not known to date

4.3 Indication of any immediate medical attention and special treatment needed none

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Co-ordinate fire-fighting measures to the fire surroundings water spray, foam, dry extinguishing powder, carbon dioxide (CO₂)

Unsuitable extinguishing media water jet

5.2 Special hazards arising from the substance or mixture

Non-combustible.

Hazardous combustion products in case of fire and/or explosion do not breathe fumes

5.3 Advice for firefighters

Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel. Avoid contact with skin and eyes.

6.2 Environmental precautions

Keep away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill. Covering of drains.

Advice on how to clean up a spill. Wipe up with absorbent material (e.g., cloth, fleece).

Other information relating to spills and releases.

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10.

Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

No special measures are necessary.

Advice on general occupational hygiene

Wash hands before breaks and after work.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice

Ventilation requirements

Use local and general ventilation.

Specific designs for storage rooms or vessels
Recommended storage temperature: 2 – 30°C.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters Limit:

No information found

8.2 Exposure control

Engineering Control:

Provide adequate ventilation. Where reasonably practicable, this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and solvent vapor below the OEL, suitable respiratory protection must be worn.

Ensure that eyewash stations and safety showers are proximal to the work-station location.

Respiratory Protection: Wearing filter mask.

Eyes Protection: Wear protective goggle in working time. (Comply with the European Union EN 166 or The U.S. NIOSH standard.)

Hands Protection: Wear protective gloves (such as butyl rubber), pass the tests according to EN 374 (EU), US F739 or AS/NZS 2161.1 standard.

Sanitary Measure: Forbid smoking, Washing hands after handling products.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Buffer:

Appearance and Color: Light yellow liquid

Odor: Odorless

PH value: 7.0-8.5

Flammability: Nonflammable

Density (g/cm³): 1.0

Relative steam density (air = 1): No Data

Vapor pressure (MPa): No Data

Octanol/water partition coefficient : No Data

Viscosity (mPa/s): No Data

Flash point (°C,Closed cup): Not applicable

Boiling point (°C): No Data

Freezing point (°C): No Data

Evaporation rate (kg/s): No Data

UEL %(V/V): Not applicable

LEL %(V/V): Not applicable

Auto-ignition temperature (°C): Not applicable

Decomposition temperature (°C): Not applicable

Solubility: Miscible with water

Test Kit:

Appearance, Color, Odor, Flat, white plastic housing containing white, narrow membrane test strip is odorless.

pH: no data available

Boiling Point: no data available

Melting Point: no data available

Flash Point: 200°C (nitrocellulose membrane)

Ignition temperature: no data available

Low Explosion Limit: no data available

High Explosion Limit: no data available

Vapor pressure (kPa): No data available.

Vapor density (air = 1): No data available

Relative density (water = 1): No data available

Solubility (mg/L): No data available.

Octanol/water partition coefficient: No data available

Auto-ignition temperature (°C): No data available

Decomposition temperature (°C): No data available

Viscosity: No data available

Others: Resistance value: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

Not classified based on available information.

Components:

Tween-20

Acute toxicity: LD50 Oral-rat-40,554.0 mg/kg

Inhalation: no data available

Dermal: no data available

Skin corrosion/irritation: no data available

Components:

Tween-20

Skin-Human

Result: Mild skin irritation-3d

Serious eye damage/irritation:

No data available

Respiratory or skin sensitization:

No data available

Germ cell mutagenicity:

No data available

Carcinogenicity:

Components:

Tween-20

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.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity:

No data available

No data available

Specific target organ toxicity-single exposure

No data available

Specific target organ toxicity-repeated exposure

No data available

Aspiration hazard.:

No data available

Additional Information

RTECS:TR7400000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Tween-20.

Toxicity to fish LC50-other fish-350 mg/l-24h

Toxicity to daphnia and other aquatic invertebrates

No data available

Toxicity to algae

No data available

Toxicity to bacteria

No data available

12.2 Process of degradability

The methods for determining biological degradability are not applicable to inorganic substances.

12.3 Bio accumulative potential

No data available.

12.4 Mobility in soil

Data is not available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

Data is not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Handling waste according to the local regulations. Contact specific waste disposal company or companies recommended by local laws.

13.2 Handling method for uncleaned packaging:

According to official regulations.

SECTION 14: Transport information

14.1 UN NO.:

Not regulated as a dangerous good

14.2 Transport hazard class:

Not regulated as a dangerous good

14.3 Packaging group:

Not regulated as a dangerous good

14.4 UN proper shipping name:

Not regulated as a dangerous good

14.5 Environmental hazards:

Not regulated as a dangerous good

14.6 Special precautions for user:

Remarks: Not dangerous goods in the meaning of ADR/RID, DN,IMDG-Code,ICAO/IATA-DGR

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

Remarks: Not applicable

14.8 Attention Notes:

THE CONSIGNMENT IS NOT CLASSIFIED AS DANGEROUS UNDER THE 61ST EDITION OF THE IAT, A DANGEROUS GOODS REGULATIONS AND ALL APPLICABLE CARRIER AND GOVERNMENTAL REGULATIONS.

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorization (Article 59).

Not applicable

REACH - List of substances subject to authorization (Annex XIV)

Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer

Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants

Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)

Conditions of restriction for the following

Entries should be considered: Number on list 3

AICS: Not in compliance with the inventory

NZIoC: Not in compliance with the inventory

ENCS: Not in compliance with the inventory

ISHL: Not in compliance with the inventory

KECI: Not in compliance with the inventory

PICCS: Not in compliance with the inventory

IECSC: Not in compliance with the inventory

TCSI: Not in compliance with the inventory

TSCA: Substance(s) not listed on TSCA inventory

Volatile organic compounds: Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)

Remarks: Not applicable

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

15.2: Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

The information in this Material Safety Data Sheet 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. This information is furnished upon condition that the person receiving it shall make his own determination of the suitability of the material for his particular purpose.