

SAFETY DATA SHEET

COVID-19 Antigen Detection Kit
DNA Diagnostic A/S

Revised: 05.11.2020
Replaces: NA

1. Product Identification

Product names:

COVID-19 Antigen Detection Kit

Catalog no's.:

CV19IC

Chemical names, common names:

Not applicable

Product use:

The product is used for detection of SARS-CoV-2 N-protein in respiratory tract samples. The kit is CE-marked and labeled IVD "For in-Vitro Diagnostic procedures"

Synonyms:

Not applicable

Manufacturer's name:

DNA Diagnostic A/S

Address:

Voldbjergvej 14
DK-8240 Risskov
Denmark

Business phone: +45 8732 3050

Emergency phone: Use your local number

2. Hazards identification

Classification of the substance or mixture according to 1272/2008 CLP

Not classified.

Label Elements 1272/2008 CLP

Not classified.

Other Hazards

The product does not meet the criteria for PBT or vPvB.

3. Composition / Information of Ingredients

The COVID-19 Antigen Detection Kit consists of the following components:

Component

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Detection card – 50 pieces
Buffer ampoule – 50 ampoules
Drip lid – 50 drip lids
Tube – 50 tubes
Swab – 50 swabs

Composition:

Detection card: Plastic part of detection card contains Sodium Azide. CAS-No: 26628-22-8 Quantity: < 0.0001%. This is below the notifiable threshold for this substance.

The test strip containing dry reagents (antibodies) is placed in a plastic device and stored in a sealed foil pouch containing desiccant.

Buffer contains no notifiable substances.

Special note regarding Biological Constituents

The Biological Constituents of this product are known to be non-infectious and non-hazardous. When this product is used in conjunction with bodily fluids UNIVERSAL PRECAUTIONS SHOULD BE IMPLEMENTED.

4. First aid measures

Basic hygiene should prevent any problems. If contact with this product leads to reddening, inflammation, or other skin or eye irritation, flush the exposures area with running water.

Remove any contaminated clothing, taking care not to contaminate eyes. If chemical is in eyes, open victim's eyes while under gentle running water. Use sufficient force to open eye lids. Have the victim "roll" eyes. As per standard industrial practice, the recommended minimum flushing time is 15 minutes.

The victim should seek immediate medical attention if an adverse reaction has occurred. A copy of label and SDS should be given to the physician or health professional. If chemical is swallowed, and the victim is having a reaction to the product, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow.

Eye:

Flush with water in eyewash for at least 15 minutes, holding eyelids open. Remove contact lenses, clean before re-use. Obtain medical attention if symptoms develop (redness, itching, etc.)

Skin:

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Wash with plenty of soap and water for at least 15 minutes. Remove contaminated clothing, which may be washed for re-use. Obtain medical attention if symptoms develop (redness, itching, etc.).

Inhalation:

Remove person to fresh air. Obtain medical attention unless effects are mild and temporary.

Ingestion:

Give plenty of water, if conscious. If vomiting occurs naturally, wash out mouth. Be prepared to induce vomiting upon a physician's advice. Obtain medical attention if symptoms develop.

Note to Physician:

Treat symptomatically. No specific antidote.

5. Fire Fighting Measures

Fire extinguishing media

This Product is not combustible. If this product is in the proximity of a fire, use fire extinguishing materials which are appropriate the materials which are involved in the fire, eg. powder, foam, CO₂ or water fog.

Unsuitable extinguishing media

None known.

Hazardous Combustion products

Includes carbon dioxide, carbon monoxide, and dense smoke.

Advice for firefighters

Standard turnout gear ("bunker gear"). Positive pressure self-contained breathing apparatus. Prevent firefighting water from entering the environment.

6. Accidental release measures

Personal Protective Equipment

Area ventilation is generally adequate. Chemical-resistant gloves should be worn. Wear standard safety goggles or glasses. All watertight materials and rubber materials offer adequate protection. Avoid contact with eyes and skin.

Spill cleanup

Absorb spill. Common absorbent materials should be effective. Deposit in appropriate containers for removal and disposal. Wash area with plenty of water.

Environmental precautions

Avoid discharge to lakes, streams, sewers, etc. Accidental releases may be subject to special reporting requirements and other regulatory mandates.

See also sections 8 and 13

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7. Handling and storage

Storage of some materials is regulated by federal, state, and/or local laws.

Precautions for safe handling

See section 8 on exposure controls /personal protection for information on personal protection. Avoid contact with eyes and skin. The product should be used under well-ventilated conditions. Keep closed or covered when not in use.

Storage temperature

Room temperature

Storage pressure

Ambient.

Handling procedures

Keep closed or covered when not in use.

Storage Procedures

Suitable for most general chemical storage areas. Protect from direct sunlight.

Specific end uses

This product should only be used for applications described in section 1.

8. Exposure controls, personal protection

Control parameters

Occupational exposure limits

Sodium azide in the detection card: OMSHA PEL 0.3 mg/cubic meter CL ACGIH, TLV: TWA Ceiling Limit 0.1 ppm.

DNEL/PNEC: -

Exposure controls

Appropriate technical measures:

Well-functioning area ventilation is generally adequate. No respiratory protection will be needed under normal operating conditions to protect from product. Follow your local biosafety regulations for protection against SARS-CoV-2 from the person to be tested.

General information/hygiene measures:

Smoking, consumption of food or liquid, and storage of tobacco, food or liquid, are not allowed in the workroom. Whenever you take a break in using this product and when you have finished using it, all

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exposed areas of the body must be washed. Always wash hands, forearms and face. Make sure that eyewash and emergency showers are clearly marked. Avoid contact with eyes and skin.

Personal Protective Equipment

Only CE marked personal protection equipment should be used.

Wear standard safety goggles or glasses (EN 166). No respiratory protection is needed to protect from product. Follow your local biosafety regulations for protection against SARS-CoV-2 from the person to be tested.

Wear appropriate protective clothing for protection against SARS-CoV-2 from the person to be tested.

9. Physical and chemical properties

For buffer component of the kit

Odor

none

Boiling point

100 degrees Celsius

Melting point or range

0 degrees Celsius

pH

neutral

Vapor pressure

Not established but similar to water

Specific gravity

1.0

Solubility in water

Yes

Vapor pressure, mm Hg at 20 degrees Celsius

Similar to water

Volatiles

Not established

Evaporation rate (water=1)

Not established

Viscosity

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Not established

Appearance and color

Colorless liquid

10. Stability and Reactivity

Reactivity

Stable under normal and recommended conditions.

Chemical Stability

Stable under recommended conditions for use and storage

Conditions to avoid

Any set of conditions, which should be avoided for water. Direct sunlight. Strong oxidizers and reducers. Strong acids and bases. Alkalimetals.

Materials with which substance is incompatible

This product is not compatible with substances which are incompatible with water. Otherwise not established.

Hazardous Decomposition Products

None known

Hazardous reactions

Not expected to occur

11. Toxicological information

Potential Health Effect

No long-term health effect from exposure to this product is presently known.

Specific target organ toxicity – single exposure

Not classified

Acute toxicity

Not classified

Serious eye damage/irritation

Not classified

Dermal/skin corrosion/irritation

Not classified

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Inhalation/respiratory

Not classified

Oral/ingestion

Not classified

Aspiration hazard

Not classified

Specific target organ toxicity – single exposure

Not classified

Specific target organ toxicity – repeated exposure

Not classified

Carcinogenicity

Not classified

Reproductive toxicity

Not classified

Additional information

Not applicable

12. Ecological Information

Toxicity

Not classified but avoid leakage to sewage system or surface water.

Environmental Fate (Degradation, Transformation, and Persistence)

Bio-concentration is not expected to occur

Bioaccumulative potential

Bioaccumulation is not expected to occur

Mobility in soil

No data

Result of PBT and vPvB assessment

The product does not meet the criteria for PBT or vPvB

Other adverse effects

None known

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13. Disposal Considerations

Waste treatment methods

Avoid discharge to drain and surface water Collect spills and waste in closed leak-proof containers for disposal at the local hazardous waste site.

EWC-code

15 02 02 absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances.

Contaminated packing

Packaging which contains leftovers from the product must be disposed of in the same way as the product.

14. Transport information

This product is not subject to transport regulations

UN Proper shipping name

Not determined

UN number

Not determined

Transport Hazard class

Not determined

Environmental hazards - MP

Not determined

ID number

Not determined

Special precautions for the user: Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and IBC code: Not applicable

15. Regulatory information

European Union.

Pressure Equipment (Amendment) Regulations 2011. Chemicals (Hazard Information and Packaging for Supply) Regulations 2009. Control of Substances Hazardous to Health Regulations 2002 (as amended). Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (as amended). Personal Protective Equipment

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Regulations 2002. Personal Protective Equipment at Work Regulations 1992. Hazardous Waste (England and Wales) Regulations 2005(as amended). EC regulation 19s07/2006 (REACH) Directive 2000/532/EC. Seveso directive: 96/82/EC. EU 453/2010.

United States.

TSCA: This product is solely for research and development purposes only. It may only be handled by technically qualified individuals.

Canada.

DSL/NDSL: Not determined.

16: Other information

The above information was acquired by diligent search and/or investigation and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since DNA Diagnostic A/S cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. THE INFORMATION IN THIS SDS DOES NOT CONSTITUTE A WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.