

Clarity Diagnostics LLC

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SAFETY DATA SHEET

1. Identification

Product Name: Clarity COVIBLOCK™ COVID-19 IgG/IgM Test Cassette (Lateral Flow Method)
Cat No.: CD-COV19 (SDS for Test Cassettes and Buffer)

Recommended Use of the Chemical and restrictions on use:

In-vitro diagnostic medical device

Manufactured by:

Salofa Oy
Örninkatu 15,
24100 Salo

Marketed by:

CLARITY DIAGNOSTICS LLC
1060 HOLLAND DRIVE, STE A and D
BOCA RATON, FLORIDA 33487

Emergency Information: techsupport@claritydiagnostics.com

2. Hazards Identification

Information Pertaining to Particular Dangers for Man and Environment:

The preparation is not classified as dangerous according to Directive 1272/2008/EC.

Classification System:

The classification is in line with current EC (European Community)-directives. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

3. Composition/Information on Ingredients

Chemical Characterization and Component CAS

Description:

In vitro diagnostic reagent. Aqueous preparation. The buffer contains:
Per 1000mL buffer containing

- Sodium Chloride 7647-14-5 $\approx$ 9.0 g/L
Sodium Phosphate Dibasic 7782-85-6 $<$ 6.0 g/L
Sodium Azide 26628-22-8 0.2 mg/ml
- Casein Sodium 9005-46-3 $\approx$ 5.0 g/L
- Kanamycin Sulfate 25389-94-0 0.25 g/L

Material Safety Data Sheet

according to 1907/2006/EC, Article 31

Version: Feb. 18, 2020

Product Use: *in vitro* diagnostic use only and for Professional Use only

Dangerous Components:

The preparation does not contain reportable quantities of hazardous components.

4. First Aid Measure

General Information:

If signs of infection occur, seek medical attention.

Symptoms of poisoning may even occur after several hours; therefore, medical observation for at least 48 hours after the accident.

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, immediately flush skin with cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, please gargle, vomiting is forbidden. Contact a poison control center or physician for instructions if feel uncomfortable.

5. Fire-fighting Measures

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

When heated to decomposition, may product carbon oxides, nitrogen oxides(NOx), sulfur oxides, hydrogen chloride gas.

Material Safety Data Sheet

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Standard Protective Equipment and Precautions for Firefighters:

Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental Release Measures

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

This preparation contains a small amount of proclin 300 which is toxic to aquatic life. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and Materials for Containment and Clean-Up:

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

Reference to other sections

For disposal see section 13.

7. Handling and Storage

Handling:

Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2°C ~ 30°C. See Section 10.

8. Exposure Controls/Personal Protection

Components 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 in the workplace.

Additional information: The lists that were valid during the compilation were used as basis.

Personal Protective Equipment (PPE):

Material Safety Data Sheet

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Version: Feb. 18, 2020

General Protective and Hygienic Measures:

Adhere to good laboratory practices (GLP).

Wash hands during breaks and at the end of the work.

Breathing Equipment:

Not necessary, if room is well-ventilated.

Take precautions, if chemical concentrations exceed the exposure limits (if any) listed above.

Protection of Hands:

The gloves serve to protect the user against splashes. For safety reasons they should be changed immediately after wetting.

Since the product is in fact a preparation out of several substances, no specific information can be given on the permeation breakthrough time. The choice of suitable gloves depends not only on the material, but also on other quality features and must, therefore, be checked with the respective manufacturer. As far as we know, disposable gloves, among other things out of nitriles, are suitable. Nevertheless, this recommendation is not intended to replace a suitability test, which is essential and must be carried out under the respective conditions of use.

Eye Protection: Safety glasses recommended during refilling.

9. Physical and Chemical Properties

Appearance:	Clear, colorless liquid	pH:	7.4 (approximate)
Odor:	Not available	Solubility:	Water-soluble
Specific Gravity:	Not available	Vapor Pressure:	Not available
Boiling Point:	Not available	Partition Coefficient (n-octanol/water):	Not available
Melting Point:	Not available	Vapor Density:	Not available
Freezing Point:	Not available	Chemical Family:	Alkaline solution
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not available		
Flash Point:	Not available		

10. Stability and Reactivity

Chemical Stability: Stable under ordinary conditions of use and storage. See Section 7.

Material to be Avoided: No data about it.

Hazardous Reaction: No data about it.

Material Safety Data Sheet

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Hazardous Decomposition Products: When heated to decomposition, may product carbon oxides, nitrogen oxides (NOx), sulfur oxides, hydrogen chloride gas. See section 5.

11. Toxicological Information

Acute Toxicity: Quantitative data on the toxic effects of this product is not available.

Primary Irritant Effect:

- **After Skin Contact:** No irritating effects anticipated.
- **After Eye Contact:** No irritating effects anticipated.
- **After Ingestion:** Possible systemic effects following ingestion of substantial quantities: headache, dizziness, nausea, vomiting, CNS disorders, drop in blood pressure, cardiovascular failure, collapse.
- **Sensitization:** No sensitizing effect known.

12. Ecological Information

- **General Notes:** Generally not hazardous for water.

13. Disposal Considerations

Product: buffer solution

General Notes:

In general laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations.

European Waste Catalogue:

Please consult the responsible regulatory body for the assignment of disposal codes according to European Waste Catalogue.

Following Waste Disposal Key Number Are Possible:

18 01 07 chemicals other than those mentioned in 18 01 06.

Packaging's:

Disposal must be made in accordance with the local waste management regulations.

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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Version: Feb. 18, 2020

14. Transport Information

Land Transport ADR/RID (Cross-Border)

- ADR/RID-GGVSE Class: -
- Remarks: not restricted
- IMDG Class: -
- Marine pollutant: No

Air Transport ICAO-TI and IATA-DGR:

- ICAO/IATA Class: -
- Remarks: not restricted

15. Regulatory Information

Designation according to EC Guidelines:

No marking required.

Water Hazard Class (Germany): WGK 1 – slightly hazardous for water.

16. Other Information

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 exist.