



SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade Name: **COVID-19 IgG/IgM Rapid Test Card**

Catalog Number: **3279**

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

Rapid Test kit for In vitro Diagnostic

1.3 Details of the supplier of the safety data sheet

Manufacturer: Biomerica, Inc.
 Address: 17571 Von Karman Avenue; Irvine, CA 92614, USA
 Phone number: Phone number is available during office hours as follows: +949.645.2111
 Fax number: +949.553.1231
 E-Mail Contact Person: RStrickland@Biomerica.com

1.4 Emergency Telephone Number

Contact the regional poison Control Center

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable
 Chemical Ingredient Chemical Data / Information
 Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008
 The product does not need to be labelled in accordance with EC directives or respective national laws.
Hazard picograms and Signal word: N/A
Hazardous components for labeling: N/A
Hazard statements: N/A
Precautionary statements: N/A

2.3 Other hazards

At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

This product is a mixture

3.2 Mixtures

| Hazardous ingredients | CAS No. | EINECS No. | REACH Registration No. | Classification: Category Codes/ Hazard statement | W/W % |
|--|------------|------------|------------------------|--|---------|
| Mixture of 5-Chloro-2methyl-4-isothiazolin-3one and 2-Methyl-2H isothiazol-3-one (3:1) | 55965-84-9 | N/A | Not available | Acute Tox. 3: H301-H311H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 | 0.001 % |



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Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1

Lowest specific concentration limits according to Table 3.1 Annex VI:

Skin Corr. 1B; H314 $C \geq 0.6 \%$

Skin Irrit. 2; H315: $0.06 \% \leq C < 0.6 \%$

Eye Irrit. 2; H319: $0.06 \% \leq C < 0.6 \%$

Skin Sens. 1; H317: $C \geq 0.015 \%$

4. FIRST-AID MEASURES

4.1 Description of first aid measures

| | |
|---------------------------|---|
| <i>After inhalation</i> | Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present. |
| <i>After skin contact</i> | Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician. |
| <i>After eye contact</i> | Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION. |
| <i>After Ingestion</i> | If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration. |

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

| | |
|--|--|
| <i>Suitable extinguishing media:</i> | The common fire extinguish media can be used |
| <i>Unsuitable extinguishing media:</i> | Not investigated |

5.2 Special hazards arising from the substance or mixture

None identified

5.3 Advice for fire-fighters

Dry-chemical fire extinguisher

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Clean up with broom.

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.



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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must be removed before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions: Note the storage conditions on product packaging.

Requirements for storage rooms and containers: Store in a cool dry place.

7.3 Specific end uses

Lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimen.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protective equipment

| | |
|--|---|
| <i>General protective and hygienic measures:</i> | Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work. |
| <i>Respiratory protection</i> | Not required |
| <i>Protective gloves</i> | Disposable gloves |
| <i>Material of gloves</i> | Latex/natural rubber |
| <i>Penetration time of glove material</i> | Gloves resistance is not critical when the product is handled according to the instruction for use. |
| <i>Eye Protection</i> | Safety glasses |
| <i>Body protection</i> | Lab coat |

8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| | |
|-----------------------------|---|
| <i>Physical State:</i> | Solid |
| <i>Color:</i> | White appearance and some content of the test strip is purple |
| <i>Odor:</i> | Odorless |
| <i>Odor threshold:</i> | Not established |
| <i>Flash point:</i> | Not established |
| <i>Self-igniting:</i> | Product is not known to be self-igniting |
| <i>Danger of explosion:</i> | There is no substance in the kit that could lead to the danger of explosion |
| <i>Melting point:</i> | Not established |
| <i>Boiling point:</i> | Not established |



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| | |
|--|--|
| <i>Vapor pressure:</i> | Not established |
| <i>Density (20°C):</i> | Not established |
| <i>pH-value at 20°C:</i> | Not established |
| <i>Solubility in water:</i> | Insoluble |
| 9.2 Other safety information: | |
| No | |
| 10. STABILITY AND REACTIVITY | |
| 10.1 Reactivity | |
| The product is stable in accordance with the recommended storage conditions. | |
| 10.2 Chemical stability | |
| All the chemicals in the test kits are stable. | |
| 10.3 Possibility of hazardous reactions | |
| Almost impossible | |
| 10.4 Conditions to avoid | |
| High humidity and the temperature out of 2-30°C | |
| 10.5 Incompatible materials | |
| No | |
| 10.6 Hazardous decomposition products | |
| No | |
| 11. TOXICOLOGICAL INFORMATION | |
| 11.1 Information on toxicological effects (Mixture) | |
| Acute toxicity: | Quantitative data on the toxic effects of this product is not available. |
| Irritation: | Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness. |
| Corrosivity: | Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed. |
| Sensitization: | Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly. |
| Repeated dose toxicity: | Not yet investigate |
| Carcinogenicity: | Not yet investigate |
| Mutagenicity: | Not yet investigate |
| Toxicity for reproduction: | No reproductive toxic effect known. |
| 12. ECOLOGICAL INFORMATION | |
| 12.1 Toxicity | |
| No data available | |
| 12.2 Persistence and degradability | |
| No data available | |



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| 12.3 Bioaccumulative potential | |
| No data available | |
| 12.4 Mobility in soil | |
| No data available | |
| 12.5 Results of PBT and vPvB assessment | |
| PBT/vPvB assessment not available as chemical safety assessment not required/not conducted | |
| 12.6 Other adverse effects | |
| No data available | |
| 13. DISPOSAL CONSIDERATIONS | |
| 13.1 Waste treatment methods | |
| <i>Product:</i> | Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. |
| <i>European waste catalogue:</i> | 18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection. |
| <i>Packaging:</i> | Disposal must be made in accordance with 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. |
| 14. TRANSPORT INFORMATION | |
| 14.1 UN proper shipping name | |
| ADR/RID: Not dangerous goods | |
| IMDG: Not dangerous goods IATA: Not dangerous goods | |
| 14.2 Transport hazard class | |
| ADR/RID: - IMDG: - IATA: - | |
| 14.3 Packing group | |
| ADR/RID: - IMDG: - IATA: - | |
| 14.4 Environmental hazards | |
| ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: <input type="checkbox"/> yes / <input checked="" type="checkbox"/> no | |
| Marine Pollutant: <input type="checkbox"/> yes / <input checked="" type="checkbox"/> no | |
| 14.5 Special precautions for user | |
| See sections 6-8 | |
| 14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | |
| Delivery will only be taken in suitable and regulatory approved packaging | |
| 15. REGULATORY INFORMATION | |
| 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture | |
| <i>EU regulations:</i> | This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. |
| 15.2 Chemical Safety Assessment | |
| The mixture was not subjected to security assessment | |



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16. OTHER INFORMATION

General information

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501]. The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.