

Safety Data Sheet

Title: **INDICAID COVID-19 IgM/IgG Rapid Test Kit SDS**

Document #: SDS-0030/ Revision. A

SAFETY DATA SHEET

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND COMPANY IDENTIFICATION

1.1 Product identifier

Product Name INDICAID COVID-19 IgM/IgG Rapid Test

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

Identified uses In vitro Diagnostics

1.3 Details of the supplier of the safety data sheet

Manufacturer Phase Diagnostics, Inc.
10527 Garden Grove Boulevard,
Garden Grove, CA 92843
USA
Phone: +1 (657) 296-6106

1.4 Emergency telephone number

Emergency Number +1 (657) 296-6106 [US]
+852 9135 2570 [Hong Kong]

Section 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.3 Other hazards

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at level of 0.1% or higher.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | %w/v |
|---|------------|------|
| Composition of Sample Buffer | | |
| NaH ₂ PO ₄ ·2H ₂ O | 13472-35-0 | 0.3 |
| Na ₂ HPO ₄ | 7558-79-4 | 1 |
| NaCl | 7647-14-5 | 8 |
| Tween-80 | 9005-65-6 | 2 |

Safety Data Sheet

Title: **INDICAID COVID-19 IgM/IgG Rapid Test Kit SDS**

Document #: SDS-0030/ Revision. A

Section 4: FIRST AID MEASURES

4.1 Description of first aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Wash off immediately with plenty of soap and water.

In case of eye contact

After eye contact: Rinse thoroughly with plenty of water, also under the eyelids for at least 15 minutes.

If swallowed

After swallowing: Never give anything by mouth to an unconscious person. Make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

Section 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Nature of decomposition products not known.

Not combustible.

Ambient fire may liberate hazardous vapours.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

Safety Data Sheet

Title: **INDICAID COVID-19 IgM/IgG Rapid Test Kit SDS**

Document #: SDS-0030/ Revision. A

Section 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

For disposal see section 13.

Section 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Do not touch the test window. Store components below 30°C. Keep dry and avoid prolonged exposure to direct light. Do not open until use.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

General industrial hygiene practice. Change contaminated clothing. Wash hands after working with substance.

Personal Protection equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU). Safety glasses.

Respiratory protection

Respiratory protection not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Skin protection

Safety Data Sheet

Title: **INDICAID COVID-19 IgM/IgG Rapid Test Kit SDS**

Document #: SDS-0030/ Revision. A

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific workplace. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Control of environmental exposure

Do not let product enter drains.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| | Absorbent Pad | Sample Buffer |
|-----------------------------|--------------------------------------|---------------------------|
| Appearance | Absorbent pad affixed to vinyl strip | Clear, transparent liquid |
| Melting point | No information available | |
| Boiling point | No information available | |
| Specific Gravity | No information available | 1.000 |
| Vapor Pressure | No information available | |
| Percent Volatile by Vol. | No information available | |
| Vapor Density | No information available | |
| Evaporation Rate | No information available | |
| Solubility in Water | Insoluble | soluble |
| Flash Point (method used) | No information available | |
| Flammable Limits – LEL, UEL | No information available | |
| Explosion Potential | No information available | |

Safety Data Sheet

Title: **INDICAID COVID-19 IgM/IgG Rapid Test Kit SDS**

Document #: SDS-0030/ Revision. A

Section 10: STABILITY AND REACTIVITY

| | |
|--|---|
| 10.1 Stability | Stable under normal handling conditions |
| 10.2 Materials to avoid | None |
| 10.3 Hazardous decomposition products | None |
| 10.4 Polymerization | Polymerization does not occur |

Section 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Principle Routes of Exposure/Potential Health Effects

| | |
|------------------------------|--------------------------|
| Eyes | No information available |
| Skin | No information available |
| Inhalation | No information available |
| Ingestion | No information available |
| Specific Effects | |
| Carcinogenic effects | No information available |
| Mutagenic effects | No information available |
| Reproductive toxicity | No information available |
| Sensitization | No information available |
| Target Organ Effects | No information available |

This product does not present a physical hazard or health hazard under anticipated use or release of the product. There is no evidence to show that the ingredient(s), comprise less than 1% (0.1%) carcinogen, could release from the mixture in a concentration that would exceed OSHA PEL or ACGIH TLV or could present a health risk. Therefore, this material is not defined as a "Hazardous Chemical" by the OSHA Hazard Communication Standard (29 CFR 1910.1200) or equivalent standards generated by State agencies.

Section 12: ECOLOGICAL INFORMATION

| | |
|---------------------------------|--------------------------|
| 12.1 Ecotoxicity effects | No information available |
| 12.2 Mobility | No information available |
| 12.3 Biodegradation | No information available |
| 12.4 Bioaccumulation | No information available |

Section 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose in accordance with local regulations

Section 14: TRANSPORT INFORMATION

14.1 UN number

Safety Data Sheet

Title: **INDICAID COVID-19 IgM/IgG Rapid Test Kit SDS**

Document #: SDS-0030/ Revision. A

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

14.5 Environmental hazards

ADR/RID: No

IMDG Marine pollutant: no

IATA: no

14.6 Special precautions for user

No data available

Section 15: REGULATORY INFORMATION

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out.

Section 16: OTHER INFORMATION

Further information

This information is based on our present knowledge. The information given is designed only as a guidance for safe handling and is not to be considered a warranty or quality specification. All materials and mixtures may present unknown hazards and should be used with caution.

DISCLAIMER: Not for household or other uses.