

iHealth® COVID-19 Antigen Rapid Test

Version 1.0

Revision Date 11/11/2021

This SDS adheres to the standards and regulatory requirements of the United States and may not meet the regulatory requirements in other countries.

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name: iHealth® COVID-19 Antigen Rapid Test
Model: ICO-3000

1.2 Relevant identified uses of the product and uses advised against

Product Use: For use with anterior nasal swab specimens; For in vitro Diagnostic Only.
Restrictions on use: Do not use product for anything outside of the above specified uses.

1.3 Details of the supplier of the safety data sheet

Company name: iHealth Labs, Inc.
120 San Lucar, Sunnyvale, CA 94086, USA
Tel: 1-855-816-7705
Fax: 650-292-2222
Email: support@ihealthlabs.com

1.4 Emergency telephone number

Emergency tel: 1-855-816-7705

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the product

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Extraction Reagent: Acute toxicity, Oral (Category 4), H302
Skin corrosion (Category 1B), H314
Skin irritation (Category 2), H315
Skin sensitization (Category 1), H317
Serious eye damage (Category 1), H318

2.2 Label elements

Hazard statements: H302: Harmful if swallowed.
 H314: Causes severe skin burns and eye damage.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.

Hazard pictograms:



Signal words: Warning

Precautionary statements: P261: Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
 P264: Wash skin thoroughly after handling.
 P270: Do not eat, drink or smoke when using this product.
 P273: Avoid release to the environment.
 P301 + P312 + P330: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
 P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
 P305 + P351 + P338 + P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
 P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.
 P501: Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS – none

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Product

Component Name	Package	Composition
COVID-19 Test Card	In foil pouch with 0.5g silica gel desiccant.	Acrylonitrile Butadiene Styrene plastic card shell, Fiberglass sample pad, Nitrocellulose membrane,

		Absorbent pad (mixture of wood pulp and cotton pulp), SARS-CoV-2 capture antibody, SARS-CoV-2 detection antibody, Rabbit IgG, Goat anti-rabbit IgG, Colloidal gold														
Extraction Reagent Tube	The tube made of LDPE contains 350 µL of extraction reagent.	<p>The main components and proportions of the extraction reagent are shown in the table below:</p> <table border="1"> <thead> <tr> <th>Chemical Name/CAS</th> <th>Concentration</th> </tr> </thead> <tbody> <tr> <td>Sodium Phosphate Monobasic Monohydrate /10049-21-5</td> <td>0.80%</td> </tr> <tr> <td>Sodium Phosphate Dibasic Anhydrous /7558-79-4</td> <td>0.70%</td> </tr> <tr> <td>Sodium Chloride /7647-14-5</td> <td>1%</td> </tr> <tr> <td>Triton X-100 / 9002-93-1</td> <td>0.10%</td> </tr> <tr> <td>ProClin 300</td> <td>0.05%</td> </tr> <tr> <td>EDTA Tetrasodium Salt/64-02-8</td> <td>0.20%</td> </tr> </tbody> </table>	Chemical Name/CAS	Concentration	Sodium Phosphate Monobasic Monohydrate /10049-21-5	0.80%	Sodium Phosphate Dibasic Anhydrous /7558-79-4	0.70%	Sodium Chloride /7647-14-5	1%	Triton X-100 / 9002-93-1	0.10%	ProClin 300	0.05%	EDTA Tetrasodium Salt/64-02-8	0.20%
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Nasal Swab	Packed envelope made of medical coated paper and PET/PE composite film.	The nasal swab consists of a foam tip and a polystyrene sampling rod.														

SECTION 4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Consult a physician. Show this material safety data sheet to the doctor in attendance. Move out of dangerous area.

Skin contact: Wash off with soap and plenty of water. Consult a physician.

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion: Never give anything by mouth to an unconscious person.
Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact: Irritation at the site of contact.

Eye contact: Risk of serious damage to eyes.

Ingestion: Irritation of the throat.

Inhalation: No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water Foam Carbon dioxide (CO₂) Dry powder

5.2 Special hazards arising from the product

Carbon oxides

Nitrogen oxides (NO_x)

Hydrogen chloride gas.

5.3 Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency Procedures

Personal precautions: Refer to section 8 of SDS for personal protection details.
Mark out the contaminated area with signs and prevent access to unauthorised personnel.

6.2 Environmental precautions

Environmental precautions: Do not discharge into drains or rivers.

6.3 Methods and material for containment and cleaning up

Clean-up procedures: Transfer to a closable, labelled salvage container for disposal by an appropriate method.

6.4 Reference to other sections

Clean-up procedures: Transfer to a closable, labelled salvage container for disposal by an appropriate method.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Handling requirements: Ensure there is sufficient ventilation of the area.

7.2 Conditions for safe storage, including any incompatibilities

Handling requirements: Ensure there is sufficient ventilation of the area.

7.3 Specific end use(s)

Handling requirements: Ensure there is sufficient ventilation of the area.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Workplace exposure limits: No data available.

DNEL / PNEC: No data available.

8.2. Exposure controls

Engineering measures: None.

Respiratory protection: None.

Hand protection: Protective gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: None.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Properties	COVID-19 Test Card	Extraction Reagent Tube	Nasal Swab
State:	Solid	Liquid	Solid
Colour:	White, Orange	Colorless, transparent	White
Odour:	None	None	None
Evaporation rate:	No data available	No data available	No data available
Oxidising:	No data available	No data available	No data available
Solubility in water:	Insoluble	Soluble	Insoluble
Also soluble:	No data available	Some organic solution	No data available
Boiling point/range °C	No data available	No data available	No data available

Vapour pressure:	No data available	No data available	No data available
Flammability:	No data available	No data available	No data available
Flash point°C:	No data available	No data available	No data available
Autoflammability°C:	No data available	No data available	No data available
Relative density:	No data available	No data available	No data available

9.2. Other information

Other information: Not applicable.

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2 Chemical stability

Chemical stability: Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

10.4 Conditions to avoid

Conditions to avoid: Heat.

10.5 Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6 Hazardous decomposition products

No data available

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Hazardous ingredients:

ProClin® 300	Oral	Rat	LD50	862 mg/kg
Triton X-100	Oral	Rat	LD50	5000 mg/kg

11.2 Symptom/routes of exposure

Skin contact: Irritation at the site of contact.

Eye contact: Risk of serious damage to eyes.

Ingestion: Irritation of the throat.
Inhalation: No data available.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity values: No data available.

12.2 Persistence and degradability

Persistence and degradability: Not biodegradable.

12.3 Bioaccumulative potential

Bioaccumulative potential: Bioaccumulation potential.

12.4 Mobility in soil

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

Other adverse effects: Toxic to aquatic organisms. Toxic to soil organisms.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal operations: Transfer to a suitable container.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

SECTION 14. TRANSPORT INFORMATION

14.1 UN number

UN number: No data available.

14.2 UN proper shipping name

Shipping name: No data available.

14.3 Transport hazard class(es)

Transport class: No data available.

14.4 Packing group

Packing group: No data available.

14.5 Environmental hazards

Environmentally hazardous: No data available.

14.6. Special precautions for user

Special precautions: No data available.

Tunnel code: No data available.

Transport category: No data available.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the product

Specific regulations: Not applicable.

15.2 Chemical Safety Assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

SECTION 16. OTHER INFORMATION

Phrases used in s.2 and s.3: H302: Harmful if swallowed.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.