MATERIAL SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture

1.1. product identifiers

Product Name: **SEROLOGICAL SARS-CoV-2 KIT BASED ON ELISA TECHNIQUE**

REARCH No.: A registration number is not available for this substance as the substance, or its uses are exempted from registration.

KIT COMPONENTS
96-wells Microplate (12x8) upholstered with Sars-Cov-2 recombinant antigen.
Wash buffer (20 X)
Antibody and sample dilution buffer (1X).
tetramethylbenzidine (TMB) chromogenic substrate
Stopping solution 0.5M sulphuric acid (H2SO4)
Positive control.
Negative control.
Calibrator.
HRP-conjugated anti-human antibody

1.2. relevant identified uses of the substance or mixture and uses advised against

Recommended use: Scientific and industrial laboratory use. For In Vitro Diagnostic Use.

1.3. Details of the suppliers of the Material Safety Data Sheet

IMMUNOSTEP, S.L.
Avd. Universidad de Coimbra, s/n.
Centro de Investigación del Cáncer (CIC)
Campus Miguel de Unamuno 37007 Salamanca-Spain
Tfn/Fax: +34 923294827

Information relative to Technical Services: https://immunostep.com

1.4. Emergency telephone number

+34917 68 98 00 // Instituto Nacional de Toxicología. Madrid

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Product Description: Mixture
Classification according to EC 1272/2008 (CLP/GHS): Not classified as hazardous per EC 1272/2008 (CLP/GHS).

2.2. Label elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS), US-OSHA and GHS.

Health hazards associated with H_2SO_4

- Corrosive to metals (Category 1), H290
- Skin corrosion (Sub-category 1A), H314
- Serious eye damage (Category 1), H318

- Hazard Symbol:

- Signal Word: Danger.
- Hazard statement:
  - H290 May be corrosive to metals.
  - H314 Causes severe skin burns and eye damage.
- Statement of precautions:
  - P280 Wear protective gloves / clothing / goggles / mask.
  - P303 + P361 + P353 in case of contact with skin (or hair): Take off immediately all contaminated clothing. Rinse the skin with water.
  - P305 + P351 + P338 + P310 in case of contact with eyes: Rinse carefully with water for several minutes. Remove contact lenses if possible. Continue washing. Immediately call a doctor.
- Other hazards which do not result in GHS classification: None.

2.3. Other hazards

For H2SO4, this mixture does not contain components that are considered to be persistent bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Adverse physicochemical, human health and environmental effects

This kit may contain material of human and/or animal origin and should be considered as potentially capable of transmitting infectious diseases. All patient samples, contaminated components, and fluids should be handled as potentially infectious. Follow Universal Precautions as necessary.

Compounds of human origin were tested and found negative for hepatitis B surface antigen (HBsAg), hepatitis C, human immunodeficiency virus and Syphilis. Nevertheless, it should be handled as a BSL-2 (Biosafety Level 2) or higher by personnel trained in the proper procedures for handling potential viral contaminants.

SECTION 3: Composition/ information on ingredients

Mixtures			
Hazardous Ingredients		**Hazard Classification of Pure Ingredients**	
Chemical Name	**% by wt**	**EU 1272/2008 CLP/GHS**	**Note**
PROCLIN® CMIT/MIT 3:1 CAS 55965-84-9	< 0.0014	Acute Tox. 3, H331; Acute Tox. 3; H311, Acute Tox. 3,H301; Skin Corr. 1B, H314; Skin Sens. 1, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410,	2,8
Sulphuric Acid (H_2SO_4) CAS 7664-93-9	5<C<20	Met. Corr. 1; Skin Corr. 1A; Eye Damage. 1; H290, H314, H318 Concentration limits: ≥ 15 %: Skin Corr. 1A, H314; 5 - < 15 %: Skin Irrit. 2, H315; 5 - < 15 %: Eye Irrit. 2, H319; ≤ 1 %: Met. Corr. 1, H290;	2

2 - Substance with Community workplace exposure limits
8 - Present at concentration below the cut-off limits.

MATERIAL SAFETY DATA SHEET

SECTION 4: First aid measures

4.1. General information: Get medical attention if symptoms occur.

- **Ingestion**: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
- **Inhalation:** If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

- **Skin Contact:** Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse.
- **Eye contact**: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses.

4.2. Most important symptoms and effects, both acute and delayed:

No adverse symptoms or effects have been identified.

4.3. Indication of any immediate medical attention and special treatment needed:

No data available

SECTION 5: Firefighting measures

5.1. General Fire Hazards:

Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water spray to keep fire-exposed containers cool.

5.2. Extinguishing Media In case of fire:

Use carbon dioxide (CO2), dry chemical, water spray or appropriate foam. For large fires use fire-extinguishing media appropriate for surrounding materials.

5.3. Special hazards arising from the substance or mixture Special Fire and Explosion Hazards:

No special hazards determined. Fire or excessive heat may produce hazardous decomposition products.

5.4. Hazardous Combustion Products:

No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.5. Advice for fire fighters (Protective Equipment):

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces.

5.6. Additional information:

No data available.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

Contact local authorities in case of spillage to drain/aquatic environment. Ensure suitable personal protection (including respiratory protection) during removal of spillages in a confined area.

6.2. Methods and material for containment and cleaning up:

Absorb spillage with suitable absorbent material. Prevent runoff from entering drains, sewers, or streams.

6.3. Environmental Precautions:

Do not allow the undiluted product to enter sewers/surface or ground water. As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Dispose of contents/container in accordance with local regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Use personal protective equipment as required. Universal precautions should be followed when using this product. This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2. Conditions for sale storage, including any incompatibilities

To maintain product quality, store according to the instructions in the product labeling. Store in a cool, dry place. Keep container closed.

7.3. Specific end use (s)

No further relevant information available.

SECTION 8: Exposure controls/ personal protection

8.1. Components with limit values that require monitoring at the workplace:

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

Component	No. CAS	Base
Sulphuric Acid	7664-93-9	Europe. COMMISSION DIRECTIVE 2009/161 / EU establishing a third list of indicative occupational exposure limit values in application of Council Directive 98/24 / EC and amending the Commission Directive 2000/39 / CE. Chemical agent for which the EU established an indicative limit value at the time. All these chemical agents are listed in at least one of the indicative limit value directives published so far.

8.2. Engineering Controls:

No special engineering controls are required. Use with good general ventilation.

- Eye Protection: Safety glasses should be worn to prevent eye contact. Refer to European Standard EN166 or appropriate government standards.
- Skin Protection: Wear protective clothing and impervious gloves, as appropriate. Wash hands after contact.

- Respiratory Protection: Under normal conditions, the use of this product should not require respiratory protection. Use in well ventilated area.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

- Physical state: Not applicable
- Color: No data available.
- Odor: Odorless

pH: No data available.

Melting point/freezing point: No data available.

Initial boiling point and boiling range: No data available.

Flash Point: No data available.

Evaporation rate: No data available.

Flammability (Solid, Gas): Not applicable

Flammability Limits: Not applicable

Vapor pressure: No data available.

Vapor density: Not determined.

Decomposition temperature: Not applicable

Solubility (ies): No data available.

Viscosity: Not determined

Oxidizing Properties: Not applicable

Auto-ignition temperature: No data available.

9.2. Other information

Information regarding physical hazard classes: No further relevant information available.

Other safety characteristics: No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity:

Stable under normal temperature conditions and recommended use. No further relevant information available.

10.2. Chemical Stability:

The product is stable in accordance with recommended storage conditions.

10.3. Possibility of hazardous reactions:

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

10.4. Conditions to avoid:

Avoid exposure to high temperatures or direct sunlight. Avoid contact with incompatible materials.

10.5. Incompatible Materials:

Strong bases compounds.

10.6. Hazardous Decomposition Products:

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

SECTION 11: Toxicological information

11.1. Toxicity Data for Hazardous Ingredients

PROCLIN CMIT/MIT 3:1
CAS 55965-84-9

Primary Routes of Exposure:

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Delayed and immediate effects and also chronic effects from short and long term exposure:

Short term exposure

- Potential delayed effects: Mixture. Not available.
- Potential immediate effects: Mixture. Not available.

Potential immediate effects

- Long term exposure: Not available.
- Potential delayed effects: Not available.

Acute toxicity estimates: Ingredients:

Ethanediol		
Oral Dermal	LD50 LD50	> 4500 mg/kg (rat) > 3500 mg/kg (mouse)
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1)		
Oral	LD50	53 mg/kg (rat)

Potential chronic health effects

- General: No known significant effects or critical hazards.
- Skin Corrosion/Irritation: No known significant effects or critical hazards.
- Serious eye damage/eye irritation: No known significant effects or critical hazards.
- Respiratory/skin sensitization: No known significant effects or critical hazards.
- Carcinogenicity: No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP,
- OSHA or 1272/2008 EC regulation.
- Germ cell mutagenicity: No data available.
- Reproductive Toxicity: No data available.
- Specific target organ toxicity – single exposure: Not classified based on available data.
- Specific target organ toxicity – repeated exposure: Not classified based on available data.
- Other Information: None known.

Sulphuric Acid
CAS 7664-93-9

Primary routes of exposure:

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Information on toxicological effects

Acute toxicity: Mixture, No data available

Potential chronic health effects:

- Skin corrosion / irritation: Skin - Rabbit. Result: Extremely corrosive and destructive to tissues.
- Inhalation: No data available.
- Serious eye damage / irritation: Causes serious eye damage.
- Respiratory or skin sensitivity: No data available.
- Germ cell mutagenicity: Ames Salmonella typhimurium test. Negative result
- Carcinogenicity: No component of this product, which presents levels greater than or equal to 0.1%, is identified as a probable, possible or confirmed human carcinogen by the (IARC) International Agency for Research on Carcinogens.
- Reproductive toxicity: No data available.
- Specific target organ toxicity: single exposure: No data available
- Specific target organ toxicity: repeated exposure: No data available
- Respiratory hazard: No data available.

Warnings about this substance in its pure state

- The product causes severe destruction of the tissues of the mucous membranes, the upper respiratory tract, the eyes and the skin., Spasms, inflammation and edema of the larynx, inflammation and edema of the bronchi, pneumonitis, pulmonary edema, burning, cough, wheezing, laryngitis, respiratory failure, headache, nausea, vomiting. The effects may not be immediate.
- Based on information, the chemical, physical and toxicological properties may not have been thoroughly investigated.
- After inhalation of aerosols: damage to the affected mucosa.
- After contact with the skin: severe burns with scab formation. After eye contact: burns, corneal injuries.

- After ingestion: severe pain (danger of perforation), malaise, vomiting and diarrhea.
- After a latency period of a few weeks, the possibility of narrowing of the stomach outlet (pyloric stenosis).
- Other dangerous properties cannot be excluded.

Handle with adequate industrial hygiene precautions, and respect safety practices.

11.2. Information on other hazards

Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f).

SECTION 12: Ecological information

12.1. Hazards to the aquatic environment:

No data available

12.2. Persistence and Degradability:

Expected to be readily biodegradable

12.3. Bioaccumulative potential:

No data available

12.4. Mobility in soil:

No data available

12.5. Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6. Other adverse effects:

The product is not expected to be hazardous to the environment.

SECTION 13: Disposal considerations

13.1. General information:

Chemical residues and remains should be routinely handled as special waste. Must be specially treated adhering to official regulations. This material must be disposed in accordance with all local, state and provincial regulations. Do not allow product to reach sewage system.

13.2. Uncleaned packaging:

Disposal must be according to state and local regulations.
Recommended cleaning agent: Water, if necessary with cleaning agents.

MATERIAL SAFETY DATA SHEET

SECTION 14: Transport information

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

- Non-hazardous for road transport.
- Non-hazardous for sea transport.
- Non-hazardous for air transport.

SECTION 15: Regulatory information

EU Regulations. This MSDS complies with EC Regulations 1907/2006 (REACH) and amendments.
REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.
Regulation (EU) 2019/1148. No ingredients listed.

SECTION 16: Other information

The above information represents the best information currently available for us. However this reagent may present unknown hazards and should be used with caution. Independent professional opinions regarding the risk or exposure to this solution are the responsibility of the user.

CHANGE REVISION CONTROL

Change	Version	Date of revision
Document emission	1	18-10-2023