SECTION 1: Identification of the substance/mixture

1.1 product identifiers

Product Name: **SEROLOGICAL DIAGNOSTIC OF SARS-COV-2 MULTIPLEX ASSAY**

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

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: tech@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)

KIT COMPONENTS
Magnetic polystyrene microbeads coated with Sars-CoV-2 antigens.
Sample diluent buffer: sample diluent to minimize nonspecific binding and cross-reactivity in immunoassays
Wash Buffer: sodium phosphate buffer with BSA. Contains KATHON™ as preservative.
Fluorochrome conjugated anti-human antibodies in aqueous solution with 0,09% of sodium azide.
96 well plate for plate assay.

Positive and negative controls. contain CMIT/MIT 1:3

Health hazards associated with H_2SO_4: none

2.2 Label elements

- Hazard Symbol: None
- Signal Word: None
- Hazard statement: None
- Statement of precautions: None
- Other hazards which do not result in GHS classification: None.

2.3 Other hazards

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.

This product contains concentrations of azide below the hazardous level which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

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**
CMIT/MIT (5-Chloro-2-Methyl-4-isothiazolin-3-one/2-Methyl-2H -isothiazol-3-one) CAS 55965-84-9	< 0.0014	Skin irritation (Category 2), H315 Eye irritation (Category 2), H319 Skin sensitization (Category 1), H317 Short-term (acute) hazard to the aquatic environment (Category 1), H400 Long-term (chronic) hazard to the aquatic environment (Category 3), H412	2,8

KATHON™ 893MW biocide EPA Reg. No. 707-195	< 0.0014	Acute Tox. 4, H302; Acute Tox. 4; H312, Acute Tox. 4,H332; Eye Irrit. 2, H319 Skin corr. 1B H314; Skin sens.1, H317; Acute aquatic tox.1, H400; Chronic aquatic tox.1, H410, oxidizing 4, H272	2,8
Sodium Azide CAS 26628-22-8	<0.1	Acute Tox. Oral 2, H300 Aquatic Acute 1, H400 Aquatic Longterm 1, H410	2,8

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

SECTION 4: First aid measures

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.

Most important symptoms and effects, both acute and delayed:

No adverse symptoms or effects have been identified.

Indication of any immediate medical attention and special treatment needed:

No data available

SECTION 5: Firefighting measures

General Fire Hazards:

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

Extinguishing Media In case of fire:

Use carbon dioxide (CO_2), dry chemical, water spray or appropriate foam. For large fires use fire-extinguishing media appropriate for surrounding materials.

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.

Hazardous Combustion Products:

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

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.

Additional information:

No data available.

SECTION 6: Accidental release measures

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.

Methods and material for containment and cleaning up:

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

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.

- Avoid inhaling, ingestion and contact with eyes and skin.
- Do not pipette by mouth.
- Do not eat, drink or smoke in areas where kit reagents or samples are handled.
- Rubber or disposable latex gloves and protective clothing should be worn while handling kit reagents or specimens.
- Avoid splashing or generation of aerosols.

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

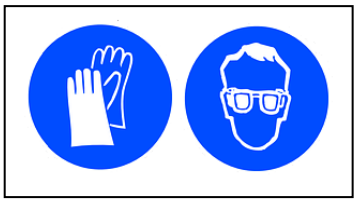
Components with limit values that require monitoring at the workplace:

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

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

Appearance

- Physical state: liquid
- 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.

SECTION 10: Stability and reactivity

Reactivity:

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

Chemical Stability:

The product is stable in accordance with recommended storage conditions.

Possibility of hazardous reactions:

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

Conditions to avoid:

Avoid exposure to high temperatures or direct sunlight.

Incompatible Materials:

Metals and metallic compounds. Strong bases.

Hazardous Decomposition Products:

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

SECTION 11: Toxicological information

Toxicity Data for Hazardous Ingredients

CMIT/MIT (5-Chloro-2-Methyl-4-isothiazolin-3-one/2-Methyl-2H -isothiazol-3-one)

CAS 55965-84-9

COMPONENT	CLASSIFICATION	CONCENTRATION
5-Chloro-2-methyl-2H-isothiazol-3-one	Acute Tox. 3; Skin Corr. 1B; Eye dam. 1; Skin Sens. 1; Acute aquatic Tox. 1; Chronic aquatic tox. 1; H331, H311, H314, H318, H317, H400, H410	≥ 1 - < 2,5%
2-Methyl-2H-isothiazol-3-one	Acute Tox. 4; Acute Tox.3; Skin Corr. 1B; Skin Sens 1; STOT SE 3; Acute aquatic Tox. 1; H302,H331, H314, H317, H335, H400	≥ 0,25 - < 1%

- **Skin corrosion / irritation:** No data available
- **Inhalation:** No data available.
- **Serious eye damage / irritation:** No data available
- **Respiratory or skin sensitivity:** No data available.
- **Germ cell mutagenicity:** No data available
- **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.

- **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.

Sodium Azide

CAS 26628-22-8: Oral LD50 Rat: 27 mg/Kg. Dermal LD50 Rabbit 20 mg/kg.

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

Potential immediate effects

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

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
- **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.

Numerical measures of toxicity:

Acute toxicity estimates: Not available.

Kathon ™ 893MW

EPA Reg. No. 707-195

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.

COMPONENT	CONCENTRATION
2-n-Octyl-4-isothiazolin-3-one	≥ 43 - < 47%
Propanediol	≥ 53 - 57%

Oral acute toxicity	LD50,Rat 760 mg/kg
Dermal acute toxicity	LD50, Rabbit 690 mg/kg
Acute inhalation toxicity	LD50, Rat after 4 hours of exposure to dust or aerosols 1,25 mg/l

- **Skin corrosion / irritation:** this reagent is corrosive
- **Inhalation:** no data available
- **Eye irritation ora cute damage**: corrosive
- **Respiratory or skin sensibility:** may cause sensitivity in contact with the skin.
- **Germ cell mutagenicity:** No data available.
- **Carcinogenicity:** No component of this product, which exhibits levels greater than or equal to 0.1%, is identified as a probable, possible, or confirmed human carcinogen.
- **Reproductive toxicity**: no data available.
- **Specific target organ toxicity – single exposure:** no data available
- **Specific target organ toxicity – repeated exposure**: no data available

SECTION 12: Ecological information

Acute hazards to the aquatic environment:

Toxic for daphnias and other aquatic invertebrates. Toxic to fish.

Toxic to algae.

Chronic hazards to the aquatic environment:

No negative effects on the aquatic environment are known

Persistence and Degradability:

Expected to be readily biodegradable

Bioaccumulative potential:

No data available

Mobility in soil:

No data available

Other adverse effects:

The product is not expected to be hazardous to the environment

SECTION 13: Disposal considerations

General information:

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.

Uncleaned packaging:

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

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

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

List of substances subject to authorization: No ingredients listed.
Chemical safety assessment: For this product a chemical safety assessment was not carried out.

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.