Trade name: HISCL™ SARS-CoV-2 Ag Assay Kit (R1 reagent)

Current version : 1.0.0, issued: 27.05.2021 **Replaced version:** -, issued: - **Region:** IE

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name

HISCL™ SARS-CoV-2 Ag Assay Kit (R1 reagent)

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

Relevant identified uses of the substance or mixture
For in-vitro diagnosis

Uses advised against
No data available.

1.3 Details of the supplier of the safety data sheet

Address
SYSMEX LTD
Sysmex House
Garamonde Drive
Wymbush
Milton Keynes
Buckinghamshire MK8 8DF
United Kingdom

Telephone no. +44 (0)333 320 3460
Fax no. +44 (0)1908 267 901

Advice on Safety Data Sheet
info@sysmex-europe.com

1.4 Emergency telephone number

For medical advice:
+353 1 809 2166 (National Poisons Information Centre)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification information
This product does not meet the classification and labelling criteria given in the Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

Not relevant

2.3 Other hazards

PBT assessment
No data available.

vPvB assessment
No data available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Hazardous ingredients
This product does not contain substances to be mentioned according to EU Regulation No 1907/2006 (REACH), annex II.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information
In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

After inhalation
Remove affected person from the immediate area. Ensure supply of fresh air.

After skin contact
Wash off immediately with soap and water.

After eye contact
Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion
Call a doctor immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
No data available.

4.3 Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media
Water spray jet

Unsuitable extinguishing media
High power water jet

5.2 Special hazards arising from the substance or mixture
In the event of fire, the following can be released: Carbon dioxide (CO2); Carbon monoxide (CO)

5.3 Advice for firefighters
Use self-contained breathing apparatus. Wear protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel
Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Do not inhale vapours.

For emergency responders
Personal protective equipment (PPE) - see section 8.

6.2 Environmental precautions
Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

6.3 Methods and material for containment and cleaning up
Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When collected, handle material as described under the section heading "Disposal considerations".

6.4 Reference to other sections
No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling
Risks inherent to handling the product must be minimised by applying the appropriate protective and preventive measures. Working processes should - so far as possible, according to the state of the art - be designed to rule out bodily contact or the release of hazardous substances.

General protective and hygiene measures
Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and

skin before breaks and after work. Do not inhale vapours. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately.

Advice on protection against fire and explosion
No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions
Keep container tightly closed in a cool, well-ventilated place.

Requirements for storage rooms and vessels
Containers which are opened must be carefully closed and kept upright to prevent leakage.

Incompatible products
Do not store together with: oxidizing agents

7.3 Specific end use(s)
No data available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
No parameters available for monitoring.

8.2 Exposure controls

Appropriate engineering controls
No data available.

Personal protective equipment

Respiratory protection
If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

Eye / face protection
Safety glasses (EN 166)

Hand protection
In case of intensive contact, wear protective gloves (EN 374). Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Other
Normal chemical work clothing.

Environmental exposure controls
No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

State of aggregation
liquid

Form/Colour
Liquid
colourless to yellow

Odour
odourless

pH value	
Value	7,5

Boiling point / boiling range

No data available

Melting point/freezing point
No data available

Decomposition temperature
No data available

Flash point
No data available

Ignition temperature
No data available

Flammability
No data available

Lower explosion limit
No data available

Upper explosion limit
No data available

Vapour pressure
No data available

Relative vapour density
No data available

Relative density
No data available

Density
No data available

Solubility in water	
Comments	soluble

Solubility
No data available

Partition coefficient n-octanol/water (log value)
No data available

Viscosity
No data available

Particle characteristics
No data available

9.2 Other information

Other information
No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity
Dangerous reactions are not expected if the product is handled according to its intended use.

10.2 Chemical stability
Stable under recommended storage and handling conditions (See section 7).

10.3 Possibility of hazardous reactions
None, when used as directed.

10.4 Conditions to avoid
None, if handled according to intended use.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

None, if handled according to intended use.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity
No data available

Acute dermal toxicity
No data available

Acute inhalational toxicity
No data available

Skin corrosion/irritation
No data available

Serious eye damage/irritation
No data available

Respiratory or skin sensitisation
No data available

Germ cell mutagenicity
No data available

Reproduction toxicity
No data available

Carcinogenicity
No data available

STOT - single exposure
No data available

STOT - repeated exposure
No data available

Aspiration hazard
No data available

11.2 Information on other hazards

Endocrine disrupting properties
No data available.

Other information
No data available.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)
No data available

Toxicity to fish (chronic)
No data available

Toxicity to Daphnia (acute)
No data available

Toxicity to Daphnia (chronic)
No data available

Toxicity to algae (acute)

No data available

Toxicity to algae (chronic)
No data available

Bacteria toxicity
No data available

12.2 Persistence and degradability
No data available.

12.3 Bioaccumulative potential
No data available.

12.4 Mobility in soil
No data available.

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	
PBT assessment	No data available.
vPvB assessment	No data available.

12.6 Endocrine disrupting properties
No data available.

12.7 Other adverse effects
No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product
Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging
Residues must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

SECTION 14: Transport information

14.1 Transport ADR/RID/ADN
The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG
The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA
The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information
No data available.

14.5 Environmental hazards
Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user
No data available.

14.7 Maritime transport in bulk according to IMO instruments
Not relevant

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)
According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation
According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES
According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances subject to restriction as listed in Annex XVII of the REACH regulation (EC) 1907/2006.

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances
This product is not subject to Part 1 or 2 of Annex I.

Other regulations
Adhere to the national sanitary and occupational safety regulations when using this product.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this mixture.

SECTION 16: Other information

Sources of key data used to compile the data sheet:
Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.
Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.
National Threshold Limit Values of the corresponding countries as amended in each case.
Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.
The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.

Creation of the safety data sheet
UMCO GmbH - D-21107 Hamburg, Georg-Wilhelm-Strasse 187, Tel.: +49(40)555 546 300, Fax: +49(40)555 546 357, e-mail: umco@umco.de

This information is based on our present knowledge and experience.
The safety data sheet describes products with a view to safety requirements.
It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

Document protected by copyright. Alterations or reproductions require the express written permission of UMCO GmbH.
Prod-ID 776300