

Trade name: HISCL SARS-CoV-2 S-IgG Assay Kit (HISCL SARS-CoV-2 S-IgG R1)**Current version :** 1.0.1, issued: 04.05.2022**Replaced version:** 1.0.0, issued: 11.08.2021**Region:** GB**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name****HISCL SARS-CoV-2 S-IgG Assay Kit (HISCL SARS-CoV-2 S-IgG R1)****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

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United Kingdom

MK8 8DF

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 (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

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**

No	Substance name	Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration %
1	sodium azide		

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26628-22-8 247-852-1 011-004-00-7 -	Acute Tox. 2*; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	< 0.50	wt%
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Full Text for all H-phrases and EUH-phrases: pls. see section 16

(*, **, ***, ****) Detailed explanation pls. refer to CLP regulation No. 1272/2008, annex VI, 1.2

Acute toxicity estimate (ATE) values			
No	oral	dermal	inhalative
1	27 mg/kg bodyweight		

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

Contain and collect spillage with non-combustible absorbent materials, e.g. sand, earth, vermiculite, diatomaceous earth and place in container for disposal according to local regulations (see section 13).

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6.4 Reference to other sections

Information regarding safe handling, see section 7. Information regarding personal protective measures, see section 8.
Information regarding waste disposal, see section 13.

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.

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

No	Substance name	CAS no.	EC no.
1	sodium azide	26628-22-8	247-852-1
	2000/39/EC		
	Sodium azide		
	WEL short-term (15 min reference period)	0.3	mg/m ³
	WEL long-term (8-hr TWA reference period)	0.1	mg/m ³
	Skin resorption / sensibilisation	Skin	
	List of approved workplace exposure limits (WELs) / EH40		
	Sodium azide (as NaN ₃)		
	WEL short-term (15 min reference period)	0.3	mg/m ³
	WEL long-term (8-hr TWA reference period)	0.1	mg/m ³
	Comments	Sk	

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

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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 pale yellow	
Odour	
odourless	
pH value	
Value	7.55 - 7.65
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	

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No data available

Kinematic 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 (result of the ATE calculation for the mixture)****No Product Name****1 HISCL SARS-CoV-2 S-IgG Assay Kit (HISCL SARS-CoV-2 S-IgG R1)****Comments**

The result of the applied calculation method according to the European Regulation (EC) 1272/2008 (CLP), Paragraph 3.1.3.6, Part 3 of Annex I is outside the values that imply a classification / labelling of this mixture according to table 3.1.1 defining the respective categories (ATE oral > 2000 mg/kg).

Acute oral toxicity**No Substance name****CAS no.****EC no.****1 sodium azide****26628-22-8****247-852-1**

LD50

27

mg/kg bodyweight

Species

rat

Source

RTECS

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

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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.

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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

The product contains following substance(s) that are considered being subject to REACH regulation (EC) 1907/2006 annex XVII.

No	Substance name	CAS no.	EC no.	No
1	Acetic acid	64-19-7	200-580-7	75
2	pepsin A	9001-75-6	232-629-3	75

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

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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.

Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)

EUH032	Contact with acids liberates very toxic gas.
H300	Fatal if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Creation of the safety data sheet

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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.

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